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2 FOOD AND DRUG  
ADMINISTRATION

0321 UNITED STATES  
DEPARTMENT OF  
AGRICULTURE P134

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6 The Microbial Safety of Fresh Produce

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8 TOWN MEETING

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12 COURT REPORTER'S TRANSCRIPT OF PROCEEDINGS

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4 TOWN MEETING

5 --oOo--

6 MR. NELSON: Good morning. I believe this  
7 is the fifth grass-roots meeting held across the  
8 country, and I do introductions.

9 I'm Ray Nelson. I'll be your moderator  
10 today, and starting to my right is Joyce Saltsman  
11 from FDA. She is one of the writers of the document.

12 Carl Winter from the California Extension  
13 Service, Tom Gardine, Director of Imports from FDA in  
14 Washington. He will be doing the presentations  
15 today.

16 Roger Lowell is the District Director of  
17 Seattle District of FDA, Acting Director of the  
18 Pacific Region at the time.

19 Dr. Richard Breitmeyer from the Department  
20 of FDA, and Dr. Vanderveen from Center for Food  
21 Safety, FDA.

22 So, welcome today. A little bit of  
23 housekeeping to start out with. Restrooms are right  
24 down the hall. So you can't miss them. There is a  
25 sign out there.

26 At lunchtime, most of the restaurants we



1 can find are on Main Street. There is Wendy's,  
2 McDonald's, Burger King -- across the street is the  
3 Dakota Jake. So there's number of restaurants out  
4 there so we try to keep that going.

5 If anyone has not received their packets  
6 yet, they are out on the table. I hope everyone  
7 has. If not, please go out and get it, and there's  
8 coffee out there. So any time you want coffee, you  
9 are free to go and get it.

10 A little history of what's going on. You  
11 know, October 2nd, 1997, President Clinton had the  
12 announcement about the initiative to, "Ensure safety  
13 of imported foods and domestic fruits and  
14 vegetables."

15 That's why you are all here. He requested  
16 that the USDA and FDA develop a guidance document for  
17 good agricultural practices and good manufacturing  
18 practices, and in that request, it was to have  
19 grass-roots meetings across the country, and like I  
20 said, this is the fifth one.

21 The sixth one is going to be held in  
22 Portland, Oregon, and a good share of the people here  
23 will be up there.

24 A lot of you probably recognize me from  
25 what we've done here in Salinas Valley. In the last  
26 two years, we worked with Western Growers, and the

1 industry here, developing a Voluntary Food Safety  
2 Guideline, this document here.

3 And we have a rollout with this document  
4 this last fall, and, basically, it talks about good  
5 agricultural practices and good manufacturing  
6 practices for the salad industry and fresh-cut  
7 industry. So there is nothing new there.

8 We also worked with the Strawberry  
9 Commission here in the State, in Watsonville, about  
10 a quality insurance program for -- ever since the  
11 Cyclospora issue happened here two years ago, and  
12 that is another document that is in process.

13 In the last document is a Quality Assurance  
14 Plan with the apple growers in El Dorado County,  
15 called, "Apple Hill Quality Assurance Plan," which is  
16 good agricultural practices and good manufacturing  
17 practices.

18 In all these documents, we give credit to  
19 the industry, to the farmers, to different groups  
20 that have worked very hard to develop this.

21 These documents, which you are looking at,  
22 the good agricultural practices document, you may see  
23 a lot of familiarity with the two of them because we  
24 have sent all this stuff back east, and the group has  
25 looked at these things. So a lot of the praise goes  
26 to the California industry here for developing these

1 kinds of documents.

2 In President Clinton's initiative, he  
3 directs the Secretary of Agriculture and Secretary of  
4 Health and Human Services to work together developing  
5 this good agriculture practices and good  
6 manufacturing practices regarding microbiological  
7 hazards and food safety and water quality, sanitation  
8 hygiene transportation, manure and municipal sewage  
9 sludge.

10 Those topics have been discussed everywhere  
11 along in our meetings, and it's a pretty common thing  
12 that we're discussing today. This is a very informal  
13 meeting. Everyone will have a chance to talk.

14 You can ask any questions you want, and you  
15 can put your comments -- if you have a comment,  
16 please go to the microphone and state your name. We  
17 have a recorder here that will be taking everything  
18 down. It will go into the record.

19 If you have written documents that you  
20 would like to have put in today, please give them in  
21 to us. We will have them put into the document. So  
22 it will be transcribed into the official document  
23 that leaves here today.

24 A few welcoming remarks now. Roger Lowell  
25 will give the first welcoming remark.

26 MR. LOWELL: Thank you, Ray. I'm a

1 stand-in for Pat Zibro, whom, many of you probably  
2 know, is the District Director in San Francisco  
3 District. I do come out of Seattle District.

4 I am quite familiar with California  
5 operations. I spent five years working in Los  
6 Angeles. I also happen to be Chair of the agency's  
7 Field Food Committee, which is the interchange  
8 between the FDA and growers for safety. So I've also  
9 been very involved. I have seen the products of your  
10 efforts down here between Ray, the State and the  
11 industry and industry associations here.

12 I've been very impressed with what you've  
13 done out here. You are leading once again. I am  
14 from Washington, so I'm not supposed to admit that  
15 California leads, but California is leading,  
16 especially in the produce area.

17 Seattle District of Food and Drug was quite  
18 involved in the apple issues because most of the  
19 samples that came out of California were run in the  
20 Seattle District Laboratory of Food and Drugs, and so  
21 we were pretty involved in that unfortunate incident  
22 also.

23 I would like to emphasize a few points  
24 about the President's initiative. First of all, it  
25 is collaborative, as Ray mentioned. This is a  
26 collaborative operation. It's not the Feds coming

1 down and dictating. It's the Feds coming out and  
2 looking for input.

3 It's also done with the Department of  
4 Agriculture and with the State organizations.

5 Town meetings, which this is one of, are  
6 rooted in the history of our country. Their purpose  
7 is to get feedback to reach a cooperative effort and  
8 to get a common understanding and a commonly-reached  
9 goal that we can move forward with, and we're also  
10 asking, as Ray indicated, for your candid input into  
11 this.

12 So please don't feel shy, after some of the  
13 presentations are made and it's open for more general  
14 comment, to get the comments in.

15 It is being recorded and your comments,  
16 each one of them, are assessed. I have had a lot of  
17 experience with the development of seafood  
18 regulations, and there was a lot of this kind of  
19 input before those regulations got developed, but I  
20 think I have to emphasize, in this case, the agency  
21 is not looking to develop regulations.

22 The agency is looking to develop  
23 guidelines, so please keep that in mind. I know  
24 there's been some rumors around that the agency is  
25 looking to develop more rules and the Feds are coming  
26 down to tell us how to do our job, and that simply is

1 not the case.

2 A couple of things about FDA's  
3 responsibility. We are responsible to see that the  
4 foods on the American tables are safe and wholesome,  
5 and part of our role is to prevent problems.

6 When I first came to the agency, more years  
7 ago I than I would hate to count right now, our only  
8 mission that I understood was to protect the public  
9 health, and we operated out of that mode of  
10 protecting the public health, and that's more of our  
11 enforcement mode.

12 About four or five years ago, a second word  
13 came into our mission statement, and that was,  
14 "Promote the public health." "Protect" did not drop  
15 out, but "promote" got added in, and I see this as a  
16 part of our role of promoting the public health is  
17 getting to the root of the problems, working with  
18 people to try to figure out how to solve those  
19 problems and then get them solved.

20 The task at hand is two-fold: First,  
21 through Tom, we plan to review some of the major  
22 features of the President's initiative on fresh  
23 produce, and we'll have that background.

24 Second, as I have said, again this is a  
25 draft and we need your information into this draft.  
26 We need your input into it and we are looking for

1       that input.

2                       What I would also ask is that in your  
3       handout, during the meeting as Tom is talking and  
4       going through it, at lunch you give that a good  
5       critical review and after that review that you come  
6       in with your comments that you want to give to us.

7                       That is all I have. Thank you for allowing  
8       me to come down, and thank you all for taking the  
9       time out of your busy schedules to come to the  
10      meeting.

11                      Ray?

12                      MR. NELSON: Thank you, Roger. The next  
13      introduction will be Dr. Vanderveen, Acting Director  
14      for Center for Food and Safety, FDA.

15                      MR. VANDERVEEN: Thank you very much.  
16      Well, welcome. We also have felt welcomed in coming  
17      here. Everyone has been very helpful in trying to  
18      arrange this meeting, and we hope that today you will  
19      feel free and capable of getting up at any time and  
20      telling us your thoughts, or asking the question that  
21      you want asked.

22                      I'm here today to welcome you on behalf of  
23      the Center for Food Safety and Applied Nutrition of  
24      the FDA, and our Federal partners in this  
25      presidential initiative, which includes, as you will  
26      learn throughout the day today, several parts of the

1 U.S. Department of Agriculture, including the  
2 Cooperative Extension, that research arm of USDA, who  
3 were there.

4 Also the Center for Disease Control is  
5 helping us in this effort and the Environmental  
6 Protection Agency will also play some role as we  
7 proceed in this general area.

8 We're -- we want to express our gratitude  
9 that you are willing to come out here today. We  
10 recognize that you have busy schedules. This is the  
11 time of year when you are still harvesting and you --  
12 some of you did travel considerable distance to get  
13 here.

14 Americans have been encouraged to consume  
15 more fresh fruits and vegetables because we recognize  
16 today, from research that has been done by the  
17 National Institute of Health, and others, that fresh  
18 fruits and vegetables are helpful in preventing  
19 long-term degenerative diseases, and we are seeing  
20 positive responses to that.

21 People are eating more fresh fruits and  
22 vegetables, and there is some progress in lowering  
23 incidences of these disease.

24 However, we are concerned about trading one  
25 risk for another risk, and we recognize that your  
26 industry has done a fantastic job. We have one of



1 the safest food supplies in the world and we want to  
2 keep it that way, but of late there's been some  
3 problems that we have been noticing.

4 It may be because we're looking better but  
5 it also may be because there are emerging pathogens  
6 that are giving us more problems.

7 So today we want to tell you about an  
8 initiative that -- and we're planning to do that,  
9 about the President's initiative in this general  
10 area, and we are here -- we also wanted to share with  
11 you the progress we're making, in terms of the  
12 guidance that we're preparing, and -- but our main  
13 purpose is to gain from you your advice, your  
14 constructive criticism, and the benefit from your  
15 knowledge. You are the folks who are busy doing the  
16 work and know what is there.

17 I also want to acknowledge the fact that,  
18 what you see today, as was already mentioned, is  
19 based in large part on what your trade associations  
20 and other industry activities have already done, and  
21 that's put together some very fine guidance in this  
22 general area, and we're trying to package it so it  
23 can be used nationwide, and perhaps internationally,  
24 to make sure that we're doing the right thing, in  
25 terms of producing guidance.

26 The educational arms of your trade

1 association have shared with us, from time to time,  
2 these guidances and asked for our input and we have  
3 tried to be helpful in that regard, but quite  
4 clearly, what you see today is what we've gleaned, to  
5 a significant degree, from what you have already  
6 done.

7 Now there is more about this new initiative  
8 that I would like to emphasize. It's about guidance,  
9 not regulation. You have already heard that. I want  
10 to tell you that the agency -- the Food and Drug  
11 Administration, and also other government agencies,  
12 are recognizing that we accomplish more through a  
13 cooperative effort, and in that regard, it's about a  
14 new paradigm, where we're trying to -- where the  
15 government will place more emphasis on helping to  
16 prevent food safety problems by establishing, in this  
17 case, good agricultural practices, guidelines and  
18 good manufacturing guidelines, and we want to  
19 approach it from that perspective.

20 We want to work with you to improve food  
21 safety. We want to establish a continuing dialogue.  
22 At the end, we're going to go through several  
23 iterations of this type of thing, and we recognize  
24 that it's a dynamic situation; that, as new science  
25 and new technology comes along, we wanted to be able  
26 to modify what we have, and the only way we're going

1 to be able to do that is by industry and government  
2 working together to do that.

3 We want to plan -- help plan, establish  
4 sound production, processing, storage,  
5 transportation, and all this is part of it, and also  
6 retail and consumer practices.

7 Now, I would caution, of course, the  
8 document that you are looking at today focuses on  
9 agriculture and production, as opposed to all the  
10 other parts of that chain, but we are going to be  
11 tackling all of that as time goes on, especially the  
12 consumer end of it.

13 One final point, although this is guidance  
14 being developed for the domestic industry and for the  
15 consumers, it is absolutely essential for us to have  
16 such guidance to be able to demand that our trading  
17 partners will meet the same standard for imports.

18 We want to work with our foreign partners,  
19 if you will, our trading partners, and make sure that  
20 we have equivalent systems, and as you will hear in a  
21 little bit, there is a move on foot.

22 The President has asked for and the  
23 Congress is responding, at least in terms of an  
24 initial bill, to give us the authority to work with  
25 other governments, to make sure that they do as good  
26 a job as you are doing, in terms of producing safe

1     produce.

2                 As you know, we can only impose such  
3     standards on our trading partners if there is  
4     equivalency, and if -- and that's what the world  
5     trade agreement, and that's what the NAFTA has at the  
6     root of it, that equivalency is the important thing.

7                 Again, I want to thank you for coming. We  
8     appreciate your input and involvement in this  
9     process, and we look forward to continuing it after  
10    today, as well.

11                Thank you.

12                MR. NELSON: Thank you, Dr. Vanderveen.

13                Our next speaker will be Dr. Breitmeyer  
14    from California Department of Food and Agriculture.

15                MR. BREITMEYER: Thank you, Ray. On behalf  
16    of Secretary Veneman, it is really a pleasure to add  
17    our welcome and share our perspective from the  
18    Department of Food and Agriculture on these important  
19    food and safety issues.

20                We are very pleased that FDA has come to  
21    California to receive input on this initiative. It's  
22    really appropriate, since California produces over  
23    50 percent of the fresh fruit and vegetables in this  
24    nation.

25                We are very proud that California has been  
26    a leader in developing food safety guidelines and

1 quality insurance programs for a wide variety of  
2 plant and animal commodities, including fresh fruits  
3 and vegetables.

4 Developing these successful partnerships  
5 has been possible through the efforts of many  
6 industry leaders, several of which you are going to  
7 hear from today. Working cooperatively with all  
8 levels of government, locally at the State level, and  
9 nationally.

10 Also working with university experts who  
11 have stepped forward to assist in the educational  
12 processes, the training programs and assisting to  
13 look at the research needs in many of these areas,  
14 cooperation between agriculture and public health  
15 agencies in California has just been excellent.

16 Solutions and programs have been developed  
17 together and we feel very strongly that that should  
18 be a model that's looked at nationally.

19 We encourage the FDA to recognize, and  
20 thank them for already recognizing, the excellent  
21 work that has been done in developing guidelines and  
22 programs that have been developed cooperatively  
23 between industry leaders, university researchers and  
24 all the government agencies here in California.

25 It's important to clearly recognize that  
26 California already has some of the most stringent

1 laws, regulations and standards already in place to  
2 protect public health and ensure food safety, as well  
3 as worker safety.

4 We encourage FDA to spend considerable time  
5 in the fields, in the processing plants with industry  
6 experts and really gain a firsthand appreciation of  
7 the standards already in place and ensure that the  
8 guidelines reflect modern agricultural practices.

9 The folks crafting this document must  
10 understand firsthand what's really going on out  
11 there. That is absolutely essential.

12 We would like to caution FDA from targeting  
13 specific guidelines for individual commodities which  
14 may inadvertently imply to consumers and unfounded  
15 risk for certain specified fruits and vegetables.

16 We do encourage FDA to promote Food Safety  
17 Guidelines applicable to all fruit and vegetable  
18 commodities, which then happens to affect all produce  
19 at each step in the food chain, from the field all  
20 the way to consumption.

21 For those issues that lack complete  
22 scientific understanding, we ask the Federal  
23 assistance in supporting and developing research  
24 which is needed to prevent or eliminate potential  
25 microbial pathogens.

26 We look forward to strengthening even more

1 our partnership among industry, academia and all  
2 levels of government here in California, as we all  
3 work together to provide our consumers with the  
4 safest possible food supply. Thank you very much.

5 MR. NELSON: Thank you, Mr. Breitmeyer.  
6 Our next speaker will be Carl Winters from UC Davis  
7 Extension.

8 MR. WINTER: Thank you, Ray. Good morning.  
9 As the designee for the University of California  
10 Cooperative Extension Services, I'm wearing a pretty  
11 big hat. I am not an administrator in the program  
12 but rather a practicing scientist with an interest in  
13 the food safety area.

14 Many of you are probably very familiar with  
15 how Cooperative Extension works in California, and I  
16 think, for issues such as this one, microbial food  
17 safety, agricultural practices, this is an area where  
18 I think the University of California can play a vital  
19 role, in many cases, developing the work and getting  
20 -- developing the research data, getting it out to  
21 the various people so we can make the best possible  
22 decision out there.

23 We've got a very large system. We have  
24 three different university campuses, Davis, Riverside  
25 and Berkeley, which have specialists in various  
26 departments which represent Cooperative Extension.

1           We also have many field stations throughout  
2 the State and, in addition, in almost all of your 58  
3 counties, we have local offices of experts who can  
4 deal with a variety of agricultural and consumer  
5 issues.

6           We are very well represented. I think our  
7 major structure is one that allows us to get out and  
8 work with a variety of different types of groups, to  
9 try to get the flow of information, whether it comes  
10 from what the government is doing, the industry is  
11 going, whether there are consumer concerns, and,  
12 hopefully, if we're doing our job right, we have a  
13 nice seamless flow system in which the appropriate  
14 research can be done, the appropriate education,  
15 campaigns, training, et cetera, can be worked out.

16           Certainly in the area of microbiological  
17 food safety, this is a critical need and something  
18 the University of California is taking very  
19 seriously.

20           I am a Director of a program on campus  
21 called the Food Safe Program, which is primarily an  
22 informational arm of the university.

23           Our goal is to try to get food safety  
24 information in appropriate format for a variety of  
25 different audiences, and in doing this, we work with  
26 people within the university, and certainly industry,



1 consumer groups, government groups, to try to put  
2 together the right groups to deal with issues.

3 We may have formal conferences in some  
4 cases, and, in other cases, we may have just  
5 newsletters or particular meetings.

6 One thing that we have just recently  
7 gotten off the ground is a Webb site. It's  
8 "foodsafety.ucdavis.edu."

9 This is all a bright-enough group. I don't  
10 have to go with "HTTP://", and all that sort of  
11 thing. Well, I had to get that in. Anyway.

12 We have just gotten that site off the  
13 ground. We have a few bugs still in it, but we  
14 certainly welcome your feedback in it.

15 We have a data base of food safety  
16 information and one of the things I think will be  
17 very valuable for many of you, and hopefully for the  
18 government agencies as well, is a directory of  
19 various food safety experts within the University of  
20 California system.

21 We have identified about 120 different  
22 people within the University of California system  
23 involved in some aspects of food safety.

24 So, you should be able to do some searching  
25 by subject matter and be able to identify the  
26 experts, both at the campus level, as well as in many

1 cases, at the local level, that can provide the  
2 appropriate information, or might be appropriate to  
3 get involved in your food safety programs.

4 We're very well represented, even at this  
5 meeting. I'd like to embarrass a couple of my  
6 colleagues by asking them to stand up.

7 In the back we have Dr. Linda Harris, who  
8 is a food safety microbiologist with Cooperative  
9 Extension Service in the Department of Food, Science  
10 and Technology. We also have Dr. Trevor Suslo, who  
11 is with the Vegetable Crops Department in Extension,  
12 who deals with a lot of post-harvest and production  
13 issues, transportation. He been very active in a lot  
14 of the food safety issues.

15 Additionally, at the local level, we have  
16 Janice Harwood, from Monterey County Cooperative  
17 Extension, who is our Consumer and Family Science  
18 Advisor.

19 So I hope, during the course of today's  
20 discussion, that you will have a chance to hear or  
21 talk to them and relay some of your concerns to them  
22 as well.

23 I really don't have too much more to say,  
24 other than that the food safety issue is certainly a  
25 major priority of the University of California  
26 Cooperative Extension System.

1           We certainly hope to be a partner with all  
2 of you, with government, with industry, with consumer  
3 organizations, to try to find the best solutions to  
4 some very serious and important problems.

5           So I look forward to working with you all  
6 in developing a lot of these good agricultural  
7 practices, and I'm very interested in the rest of the  
8 program.

9           Thank you.

10           MR. NELSON: Thank you, Carl. If everybody  
11 up here would like to sit down in the audience right  
12 now, the next speaker will be Tom Gardine, and they  
13 won't be blocking the screen.

14           MR. GARDINE: I will give everybody an  
15 opportunity to get settled. Before I begin, how many  
16 of you have had an opportunity yet to read, in any  
17 great detail, the guidance document that you would  
18 have picked up this morning?

19           Well, it's generally about half. My goal  
20 today is going to be to talk a little bit about the  
21 President's initiative, and why he is doing it, and  
22 then to go through the guidance document, to outline  
23 what we hope are some of its major components.

24           I want to stress, as I do at each meeting,  
25 please do not listen to my presentation, make a  
26 decision on that and walk out.

1           The devil in any guidance document like  
2 this, in terms of its practicality, is doability.  
3 It's financial cost to growers is in the details.

4           In putting my slide presentation together,  
5 I didn't -- the purpose of this meeting is not for  
6 you to listen to me. My only attempt is to outline  
7 the document and perhaps get discussion going. We  
8 are here to listen to you. We are here to get  
9 comments on this guidance document, to help us make  
10 it better.

11           So I will be trying to bring out points  
12 that, at other meetings, we had some discussion  
13 about, hoping to solicit comments from you, but,  
14 please, do not make a determination about the  
15 viability of the document based on what I say today.  
16 The develop is in the details.

17           Read it, and you do have an opportunity, as  
18 I will discuss later, to comment more fully on the  
19 document in writing.

20           Okay. Thank you.

21           First, a little bit about what started  
22 this. As you heard, on October 2nd, of this year,  
23 President Clinton announced his "Initiative to Ensure  
24 the Safety of Imported and Domestic Fruits and  
25 Vegetables."

26           This is an add-on component to a Food

1 Safety Initiative that he already started, called, I  
2 believe, "Food Safety from Farm to Table."

3 We realize that food safety is not  
4 something, in terms of fresh fruits and vegetables,  
5 is not something that a grower could do alone. It  
6 has a retail component -- thank you -- the  
7 President's initiative, overall initiative has a  
8 retail and consumer education component that we  
9 realize is equally important.

10 Now, why did the President feel he had to  
11 come out and do something concerning an "Initiative  
12 To Ensure The Safety Of Imported Fresh Fruits And  
13 Vegetables"?

14 When announcing this initiative, he stated  
15 fresh fruits and vegetables in this country are the  
16 safest in the world, and they are, and we want to  
17 keep them that way. But there are things that are  
18 happening that are bringing concerns with fresh  
19 fruits and vegetables to the fore that we must  
20 address, because they are affecting consumer  
21 confidence.

22 Consumer confidence in fresh fruits and  
23 vegetables are very important because, as John  
24 Vanderveen stated, your government is telling its  
25 citizens that they should be eating more and more  
26 fresh fruits and vegetables.

1           We dropped by at the local Agricultural  
2 Commissioner's office yesterday to pay a courtesy  
3 call, and I picked up this statement, not to give  
4 them any particular publicity, but -- from the  
5 California Strawberry Commission.

6           It's called, "Find the Easy Way to  
7 Five-A-Day," and what it states, and it's exactly  
8 what I'm hearing today. "Leading health association  
9 research links increased consumption of fruits and  
10 vegetables to reduced risks of heart disease and  
11 various cancers. To support these findings, the  
12 National Cancer Institute encourages Americans to  
13 consume at least five servings of fruits and  
14 vegetables every day."

15           So your government is actively encouraging  
16 its citizens to eat more fruit and vegetables. We  
17 are concerned when illnesses are associated with  
18 these. We are also concerned with the effect that  
19 these illnesses may have in consumer confidence with  
20 the product.

21           Even though we recognize that fresh fruits  
22 and vegetables in this country are damn safe, we want  
23 to see what we can do together, working with  
24 industry, academia and the States, to keep them safe.

25           The concern started with illnesses that you  
26 are all aware of. We had Salmonella associated with

1 fresh fruits and vegetables.

2 We have Cyclospora associated with  
3 Guatemalan raspberries, E. coli 0157:H7, I believe,  
4 associated with lettuce. Salmonella also associated  
5 with lettuce.

6 That's a short list, and by no means is  
7 this an endemic out-break or isolated incidences that  
8 are affecting people.

9 These diseases are terrible. You don't  
10 want to be associated with them, but it is something  
11 we have to respond to, and another reason is that  
12 some of these organisms, Cyclospora, E. coli are  
13 emerging.

14 The analytical methodology to enable us to  
15 test for them really isn't there. So our normal  
16 defense mechanism of testing product, certainly in  
17 terms of imports at the border, really don't work,  
18 because frequently the analytical methodology either  
19 doesn't exist or is, frankly, damn poor.

20 Research will fix that. By the time --  
21 but, unfortunately, frequently by the time research  
22 finds a way to test the one organism, there are new  
23 emerging pathogens that must be dealt with, and the  
24 research is very difficult because, in each different  
25 food matrix, there may be different problems in  
26 finding the organism.

1           For example, Hepatitis in strawberries,  
2       should you look for that, there is a problem because  
3       there is something in the strawberry, an enzyme or  
4       whatever, that inhibits the growth of the organism  
5       when you try to find it.

6           So the research to test it analytically is  
7       difficult. The research to test it analytically may  
8       not be the way to go because much of the  
9       contamination would be very spotty. It wouldn't be  
10      spread throughout a production lot.

11          So what the President is saying, and we at  
12      USDA in the States, and hopefully working through  
13      your trade organizations, because we do realize that  
14      the U.S. Industry was way ahead of the curve on this  
15      -- the U.S. Industry, through national industry  
16      groups and local trade associations, we're developing  
17      guidance documents to address what we'll be talking  
18      about today, a very narrowly-focused problem,  
19      microbiological hazards associated with fresh  
20      produce.

21          The industry was way ahead of us on this,  
22      addressing it before we did, and making sure that  
23      guidance was out there to assist growers to minimize  
24      the risk of this problem.

25          The President's initiative has two major  
26      components.



1           First, legislative.

2           You had heard that a piece of legislation  
3 was submitted to Congress. It has sponsors in the  
4 House of Representatives. It does not yet have a  
5 sponsor in the Senate.

6           What the legislation says is essentially  
7 addressing imports, and what it says is that, when a  
8 foreign country's system -- when either their  
9 governmental rules, regulations and infrastructure,  
10 or industry infrastructure, does not match the level  
11 of protection we want in this country, we can --  
12 should the Secretary of Health and Human Services  
13 make such a determination, not permit entry of that  
14 product.

15           The legislation, as crafted now, would also  
16 permit us to deny entry of a product, should FDA be  
17 denied an inspection in a foreign country when we  
18 believe there is a need, i.e., response to an illness  
19 out-break.

20           It also requires us to develop a plan to  
21 which pen has not yet been put to paper, to determine  
22 how to implement this legislation.

23           I must caution you, the legislation was  
24 submitted in the house. It does not yet have a  
25 sponsor in the Senate.

26           That is probably because it was submitted

1 only a day or two before Congress went out of  
2 session, but we have no idea whether the legislation  
3 will look as it does now when it is finally passed,  
4 or if indeed it will pass. So I'm sure your industry  
5 groups will keep you well advised on it.

6 The President's initiative also has an  
7 administrative component. We will be talking about  
8 the guidance, the good agricultural practice  
9 guidance, a great deal, in a moment.

10 It also will have a budget request. If we  
11 are going to initiate this, there is research that  
12 needs to be done to fill GAPS, either by the Federal  
13 Government, the State, academia, or, you know,  
14 research industries, industry itself. We do not  
15 know.

16 The budget would involve our fiscal 1999  
17 budget. Requests are in. We don't have any idea how  
18 much we're going to get, so I'm not going to talk a  
19 great deal about the budget, and President Clinton  
20 asked USDA, FDA, and other involved agencies, when we  
21 talk about water, we need EPA involvement.

22 When we talk about worker health  
23 sanitation, we need OSHA at the table, and we are to  
24 report to the President in 90 days, not what we are  
25 going to do, but an outline of what we think -- of  
26 the steps we think we have to go through to implement

1 his initiative.

2 The administrative portion of the  
3 President's initiative states that FDA, in  
4 cooperation with various components of USDA, other  
5 Federal agencies, will be working and are working  
6 with States of -- both individually and through the  
7 National Association of States Department of  
8 Agriculture, to issue within one year guidance for  
9 good agricultural practices.

10 Bear in mind, this is guidance, and  
11 guidance for good manufacturing practices, variously  
12 known as GAPs and GMPs.

13 FDA and USDA would then, after this  
14 guidance is developed, coordinate assistance and  
15 educational activities to domestic and foreign  
16 industry.

17 You can't just put guidance down. You have  
18 to work with growers, domestically, and our suppliers  
19 in foreign countries, to make this work.

20 As many people have stated, and I will  
21 state many times, we are developing guidance, not  
22 regulation. It does not impose mandatory  
23 requirements on industry, either domestic or foreign.  
24 It cannot be guidance in the U.S. and mandatory  
25 overseas.

26 It is guidance everywhere, and its goal is

1 to help firms, growers and producers identify  
2 appropriate practices to minimize microbial hazards.

3 Once again, I want to stress the document  
4 we are going to be talking about today is very  
5 limited in scope. As growers, you are aware that  
6 there are many things that you have to be aware of to  
7 produce safe produce.

8 The only thing that this guidance document  
9 attempts to address are steps you could take to  
10 minimize microbial hazards associated with fresh  
11 produce.

12 We don't talk about pesticides. We don't  
13 talk about the myriad of other things that could  
14 possibly go wrong, but we are talking about, simply,  
15 microbial hazards in fresh produce, and I want to  
16 stress, we talk about minimizing microbial hazards.

17 No one at FDA, certainly not USDA,  
18 certainly not your State representatives, and  
19 certainly not you, believe this is a sterile world.  
20 You are growing these crops on the earth, under the  
21 sky.

22 You are not expected to produce a sterile  
23 product, but we are trying to work with you to  
24 identify doable things that could help minimize  
25 microbial load of pathogens when actions are within  
26 the control of the grower.

1           The proposed broad-scope good agricultural  
2 practice guidance document is planned for issuance in  
3 1998, with a very public process, and I'll talk about  
4 this a bit more.

5           But just to let you know what has happened  
6 already, we had a public meeting on February 17th of  
7 this year, where we first talked about these  
8 concepts.

9           Last week and this week, we're having a  
10 series of regional grass-roots meetings, attempting  
11 once again to solicit the input, comments,  
12 suggestions, outrage, if necessary, of regional  
13 growers.

14           We had an international meeting in  
15 Washington this past Monday because, quite frankly,  
16 when you talk about minimizing microbial risk in  
17 fresh produce, you have to deal with our foreign  
18 suppliers, as you are well aware, because of  
19 competition, they are becoming more and more an  
20 important source of fresh fruits and vegetables in  
21 this country.

22           I believe the President in his announcement  
23 mentioned something like between 35-to-40 percent of  
24 the fresh fruits consumed in the U.S. are imported,  
25 and I think it's approximately 15 percent of the  
26 fresh vegetables.

1 But more about that in a moment.

2 This is a new slide and I put the new slide  
3 in, and I also kept the old slide, because this is a  
4 very contentious point, as a number of people have  
5 already mentioned, and we do want comment and input  
6 on this.

7 The President's directive requires that  
8 good agricultural practice guidance and good  
9 manufacturing practice guidance be developed to  
10 account for specific commodity and regional  
11 differences.

12 USDA and FDA are considering all options on  
13 how to do that, and we want comments on these  
14 options.

15 The old slide, which maybe I should have  
16 taken out, but I didn't, because we want you to think  
17 about it, used to say this:

18 "Specific good agriculture practice and  
19 good manufacturing practices for fresh fruits or  
20 vegetable products were to be identified in FY '98  
21 and work be done on them and try to identify other  
22 ones."

23 Well, at our first few grass-roots  
24 meetings, that was kind of a contentious point.  
25 Obviously, people wondered, well, if you have the  
26 broad-scope guidance out there, and you think it has

1 certain universal applicability, why not wait awhile,  
2 measure that and see if you are making progress and  
3 see if specific documents are even necessary?

4 What does it imply, if you pick a specific  
5 document -- does it make one fruit and vegetable  
6 suddenly sprout a big red sign, with a "stop" across  
7 it, if government does that?

8 We certainly do not intend it to be that  
9 way, and would not craft it that way, but you know  
10 some people, if you start doing this, someone will be  
11 first.

12 And the criteria of the deciding this has  
13 not yet been selected. But this is what we were  
14 talking about, I believe, in the first four -- I  
15 believe this slide was even up there --

16 John, was this slide used in the west one  
17 in Texas?

18 MR. VANDERVEEN: Yes.

19 DR. GARDINE: This is the challenge that we  
20 have now. We have to account for specific commodity  
21 and regional differences.

22 How do we do that? Our initial thought was  
23 to develop commodity-specific or group  
24 commodity-specific good agricultural practices.

25 But are there better ways? Are there  
26 better ways, such as working through Extension

1 Service Institutions and academia, and asking them to  
2 do the research and work on these?

3 Are there -- is it a better way not to do  
4 it at all? Although that would not enable us to meet  
5 the President's charge to us, so you know, he's our  
6 boss. You got to remember that.

7 But the timeline we were talking about, at  
8 some of the earlier meetings, and I'm saying this to  
9 be consistent throughout, was that we would try to  
10 select four commodities sometime in December, to get  
11 started on.

12 Those timelines have gone. We want to hear  
13 the comments from industry about what are the best  
14 ways to do this.

15 Is it working with trade organizations,  
16 working with regional groups, and seeing if we can  
17 work together to adopt or modify guidance you already  
18 have out there?

19 Any ideas or suggestions you have are -- at  
20 this point, we want to hear about them, and are on  
21 the table, but the key is to enable us to meet our  
22 directive, our charge from the President, account for  
23 specific commodity and regional differences.

24 One of the things we thought would be good  
25 about specific-commodity good agricultural practices,  
26 because you could really focus on what, you know,



1 might be unique practices for certain commodities,  
2 and talk about what a grower could do to limit the  
3 risk associated with certain of these practices,  
4 which you can't do in the broad-scope document we're  
5 going to be talking about today.

6 But, please, we need your ideas on this and  
7 we were -- we are listening to what we are hearing at  
8 these grass-roots meetings, and they are having an  
9 effect with us.

10 "The document is guidance and not  
11 regulation."

12 Well, what does that mean? Are you going  
13 to put it out there and walk away from it?  
14 Absolutely not.

15 We are going to be working with industry to  
16 supply outreach assistance, education, to try and  
17 encourage and work through trade organizations, to  
18 have growers adopt these practices, where feasible,  
19 for their operations.

20 I want to stress that, as we get to the  
21 good agriculture practice document, you will see it's  
22 not a one-size-fits-all document.

23 It is something that -- I was very pleased  
24 to say that I think it was at the Grand Rapids'  
25 meeting where someone -- one of the favorable  
26 comments we received was that, "It looks to be almost

1 a self-assessment that a grower should do of their  
2 operations, see where problems could develop, and  
3 then let him use his intelligence, experience,  
4 knowledge, plus the guidance to make improvements  
5 where practicable and doable."

6 That was one of the favorable comments we  
7 received, and I hope you see it the same way.

8 But we at FDA and USDA are going to have to  
9 find the best way to supply education outreach and  
10 assist the answer, and get the word out, of what we  
11 are trying to accomplish through these good  
12 agricultural practice guidance for domestic  
13 industry.

14 And if we're going to do it with domestic  
15 industry, we are going to have to do it with foreign  
16 countries.

17 So, much of the rest of this year, until we  
18 get a budget to do it, it is going to be with USDA  
19 and FDA figuring out, "What are our mutual  
20 resources?"

21 "How can we best reach the grower, both  
22 domestically and internationally, and work with them  
23 to encourage adoption of many of the principles in  
24 this guidance document"

25 We have an easier task domestically,  
26 because domestically, obviously, we have an

1 infrastructure through the Extension Service, through  
2 your trade organizations, through States, that  
3 already exists for outreach to the farmer.

4 So FDA will probably be walking, you know,  
5 to the backside, domestically, but, internationally,  
6 that infrastructure may not exist. So we'll have to  
7 figure out how to do this, and we'll have to develop  
8 training modules, and also see how we could work  
9 within international organizations, such as FAO  
10 internationally, and also with local government.

11 One more thing on the President's  
12 initiative, before we open this part of the session  
13 up to questions, is the timeline.

14 Many folks at the previous meetings, and I  
15 think we heard some of this today, were concerned  
16 about what they believed was the rush to judgment --  
17 rush to finalization of this broad-scope good  
18 agricultural practice.

19 Well, once again, let me remind you that a  
20 lot of work had been done by industry itself, a lot  
21 of damn good work, by industry itself.

22 Western Growers, United Fresh Fruits and  
23 Vegetables, local organizations, had guidance  
24 documents out there that we could plagiarize, borrow,  
25 massage only slightly, when we didn't want to  
26 absolutely plagiarize, but there was -- there is a

1 lot in our document that was taken from the very good  
2 work already done by industry.

3 So, for the broad-scope gap, we thought we  
4 could move quickly. But let's go through the  
5 timeline.

6 As I said, we first discussed what were our  
7 concepts at a public meeting in February of 1997.  
8 We then discussed this further in February with the  
9 National Advisory Committee for Microbiological  
10 Criteria in Foods at a public meeting, where they  
11 discussed what advice they could give us.

12 In December of 1997, based on what we heard  
13 at the public meeting, and from the National Advisory  
14 Committee for Microbiological Criteria in Foods, we  
15 developed the initial draft.

16 We were initially thinking, in our  
17 foolishness, to go out to growers without a draft and  
18 say, "We're with the government, we're here to help  
19 you, don't worry about this, but it's going to be  
20 okay, but we're not going to show you what it is."

21 People told me I probably wouldn't come  
22 back if I did that, so we delayed at least a week or  
23 two starting the grass-roots meetings.

24 In December we started the grass-roots  
25 meetings; we're doing them now. Everything is being  
26 transcribed. The transcriptions are available in a

1 public document, and anyone who wants them, and is  
2 willing to pay the per-page cost, can obtain them.

3 So we will be getting these transcripts  
4 back, critically evaluating all of the concepts that  
5 come out of these grass-roots meetings.

6 Plus, I want to remind you, as I said, the  
7 devil is in the details. .

8 Frequently, it's difficult to put your  
9 thoughts together in one day. The Federal Register  
10 announcement for these grass-roots meetings  
11 indicates that written comments would be accepted by  
12 December 19th.

13 As one of the drafters here, Joyce  
14 Saltsman, frequently tells me, "We never turn down a  
15 good comment."

16 So then, if things come in little later  
17 than December 19th, we would certainly consider them.  
18 Sometime late February or early March, we hope to  
19 publish in the Federal Register a notice of  
20 availability of a guidance draft document.

21 This is still a draft. We are doing all of  
22 this to have a draft document ready by late February  
23 or early March for publication.

24 The draft document goes in the Federal  
25 Register with a 45-day comment period, at which time  
26 written comments should be submitted.

1           Written comments will be evaluated, and we  
2 will use those written comments to do further  
3 manipulation on the draft document, with the goal of  
4 maybe in May or June -- this is not definite --  
5 having a second public meeting or additional  
6 grass-roots meetings, if necessary, and looking for a  
7 July publication date.

8           I want to stress, we're doing all we can to  
9 make this as transparent and public a process as we  
10 possibly can, and why?

11           Because we can't do it alone. We need the  
12 growers' knowledge, we need the growers' experience.  
13 You know what is doable. You know what is feasible.  
14 You know what will help solve the problem, probably  
15 much better than we do, and we need your thoughts and  
16 the only way to do that is through a public process.

17           With this, we traditionally take a break --  
18 not a break, but a stop, and ask if there are any  
19 comments on the process, and the President's  
20 initiative, any thoughts or questions.

21           Anybody?   Stacey?

22           DR. ZAWEL:   Thank you.   Actually, I have  
23 one.

24           DR. GARDINE:   Thank you.   Get it started.

25           DR. ZAWEL:   I am Stacey Zawel with the  
26 United Fresh Fruit and Vegetables Growers

1 Association.

2 This is actually a detail. I'm wondering,  
3 in all of these meetings, there is going to be a heck  
4 of a lot of information that the court reporters are  
5 getting down.

6 How are you guys going to -- who is going  
7 to be responsible for all that?

8 My question is -- is that it seems like  
9 such a monstrous task that it won't actually be done,  
10 and I certainly hope that that doesn't happen, and I  
11 feel sorry for the person whose job it is to do  
12 that.

13 But how, technically, do you facilitate  
14 that process?

15 MR. GARDINE: Okay. I will go over this,  
16 and if Dr. Vanderveen or Dr. Saltsman want to add  
17 anything, I will invite them to do that.

18 The Center for Food Safety and Applied  
19 Nutrition, the portion of FDA that is working on  
20 developing this guidance document, and I have to  
21 remind myself to say "guidance."

22 Being a contrarian by nature, and having  
23 been instructed to say "guidance" all the time, I  
24 still say "regulation."

25 Please ignore that. It is not a Freudian  
26 slip. It's just my contrarian nature. I don't take

1 direction well. It is not a regulation, and it is a  
2 guidance. If I slip, please forgive me.

3 The transcripts will come in. We are  
4 paying extra to get the transcripts done in five  
5 working days. A team is being put together at the  
6 Center for Food Safety to read the transcripts and  
7 pull out suggestions and ideas.

8 That's going to be the challenge of --  
9 through the end of December and early January.

10 At that point, we have been working with --  
11 I do not know whether this was done through AFDO or  
12 the National Association of States Department of  
13 Agriculture.

14 We are hoping, and I think we have a  
15 tentative commitment, to get some State agriculture  
16 people to come in and work with us, to review the  
17 comments and come up with suggestions or responses.

18 A suggestion might be to reject the  
19 comment. I mean, that is always an option, but if we  
20 believe the comments are viable and worthwhile, after  
21 a joint discussion, we will then work together and  
22 find a way to incorporate what we think are better  
23 comments into our document.

24 Anything else? John?

25 MR. VANDERVEEN: Fine.

26 MR. GARDINE: Please identify yourself from



1 the microphone, please.

2 MR. BROWN: Good morning. My name is Louie  
3 Brown with the California Farm Bureau Association.

4 In May or June, there may be a second  
5 public meeting. Who will determine what is needed?

6 MR. GARDINE: I think that will be  
7 determined based on the significance of the changes  
8 that may or may not be necessary in the document.  
9 Obviously, if everyone comments on what you have in  
10 front of you, and then we put something close to it  
11 out as a Federal Register document, as a draft, and  
12 then, after reading the comments from the draft, we  
13 decide we have to completely change, it will be kind  
14 of unfair to just go to publication without doing  
15 some sort of outreach again.

16 So that's not definite, but the key to that  
17 will be the amount of change associated with the  
18 guidance document.

19 Any other questions or comments before we  
20 continue?

21 MR. GARDINE: Okay. Can you get the lights  
22 and we'll keep going here? Once again, please bear  
23 in mind that, as we start discussing -- that's where  
24 it went. Damn it.

25 That was supposed to be my second slide in  
26 the front part. People have been coming by and

1 borrowing my slides and putting them back, and  
2 whatever, so please ignore that one.

3 We're here to talk about the guidance  
4 document that you received today, "The Guide to  
5 Minimize Microbial Food Safety Hazards for Fresh  
6 Fruits and Vegetables."

7 Once again, let me begin by saying the  
8 document is limited in scope. It's attempting to  
9 address microbial hazards associated with fresh  
10 produce. All the other things, pesticides, the other  
11 things that might be of concern to you as growers, to  
12 we as government officials, to the consumer, are not  
13 being discussed in this document.

14 Why are we doing it? I discussed this  
15 already. Recent outbreaks have raised concerns about  
16 the safety of foods, including fresh fruits and  
17 vegetables that are not processed to eliminate  
18 pathogens.

19 The only point I want to add on this is  
20 that, what makes your product unique, the consumer  
21 pops it in their mouth. It's not going to be cooked,  
22 either in -- by an industrial processing facility or  
23 the consumer's home. It's a fresh product that they  
24 are going to eat as is.

25 That's why limiting the amount of microbial  
26 load, doing what we can to control what we can, is so

1 critically important, because the normal additional  
2 protective mechanisms of, you know, boiling something  
3 and cooking it, and subjecting it to heat that will  
4 destroy microorganisms, is not here for this type of  
5 product.

6 Well, I always get ahead of myself. Fresh  
7 fruits and vegetables are not subject, generally, to  
8 many of the steps designed to reduce or eliminate  
9 microbial load that processed foods receive.

10 Therefore, taking steps to reduce the risk  
11 of microbial contamination is especially important  
12 for raw produce.

13 Once again, I've got to say, it's reduced.  
14 You can't eliminate. The only time we're going to be  
15 able to talk about eliminating is when and if the  
16 science and research can find absolute control,  
17 mechanisms that would destroy the organisms in the  
18 field; not likely any time soon.

19 The best you and we can hope for is to  
20 minimize microbial risk and control.

21 A template for the document. In the  
22 document we tried to think about things that have  
23 broad applicability to the produce industry that  
24 could introduce, if not control, as well as we can,  
25 unnecessary microbial load onto the produce.

26 They are water, manure, worker, field, and

1 facility sanitation and hygiene are kind of lumped  
2 together, and transportation.

3 These were things that we thought had --  
4 well, nothing is universal, but this is what we  
5 thought were as close as -- the concepts involved  
6 here as what -- we believe are as close to universal  
7 applicability and concern for agriculture as is at  
8 all possible.

9 The guide is intended as guidance only. I  
10 believe you have heard that already. Growers are  
11 urged to take a proactive role in minimizing food  
12 safety risks.

13 This is not a one-size-fits-all document.

14 Once again, tip our hats to what industry  
15 has already done in developing specific guidance for  
16 certain crops, and their own versions of  
17 broad-scope-type guidance.

18 You are already taking a proactive role,  
19 but what we would want with this good agricultural  
20 practices and good manufacturing practices document,  
21 and the ones that are out there, it is not  
22 one-size-fits-all.

23 You really have to evaluate your own  
24 operation and figure out what you can do.

25 And the guidance that contains the best  
26 advice of FDA, USDA in consultation with industry and

1 consumer groups.

2 The document focuses -- once again, it's as  
3 broad scope, and as universal and applicable as we  
4 can make it on common elements in growing production  
5 and distribution that will reduce the risk of  
6 microbial contamination.

7 We admit in the document that many GAPS in  
8 the science lead to uncertainties in the degree of  
9 risk associated with particular farming practices.  
10 There is research that must be done.

11 One of the components of President  
12 Clinton's initiative is funding for research. We are  
13 already asking for that funding money, and trying to  
14 figure out what research is necessary, what should be  
15 our priorities? That is something that we would urge  
16 comment on also.

17 And also how to do this research.

18 When there is uncertainty, we tried in the  
19 guidance document to identify the uncertainty,  
20 recognize it where we can.

21 The guide is intended to provide practical  
22 advice appropriately qualified. We will -- and FDA  
23 and USDA are accelerating research in an attempt to  
24 answer some of the major questions that have arisen,  
25 but look at the first bulletin there, "practical  
26 advice."

1           One of the things that we need to hear from  
2 growers is, is this doable? You know, is this  
3 doable?

4           Is it practical, or, "What world do you  
5 people live in? You can't be serious about this."

6           One thing I will talk about now -- there is  
7 a slide coming up, and it had to do with the use of  
8 untreated manure on a field, and I believe that we  
9 say that, generally, there should be a minimum  
10 time frame of 40 to 60 days, but in some cases, some  
11 studies say 120 days between use of untreated manure  
12 and harvesting. And this was up in the northeast, up  
13 in Geneva, New York, and one of the growers says, you  
14 know, "Really nice advice, 40 to 60 days, maybe. But  
15 do you have any idea of what the growing season is in  
16 the northeast?"

17           And that's the sort of thing we have to  
18 hear. "It's not particularly practicable." Those  
19 are the comments that we need from you. This is --  
20 and where I can, I'll share things like that, that  
21 we've been hearing in other places.

22           One thing you must bear in mind, like  
23 everything in our society, growers are already  
24 regulated. You are dealing with IPA, you are dealing  
25 with OSHA. In some areas, guidance is already out  
26 there in the form of Federal, State and local

1 requirements.

2           Nothing in our guidance document should  
3 ever be intended or interpreted as circumventing the  
4 need for you to meet with any local, Federal or State  
5 requirements on your operation. Frequently the  
6 States and local authorities already have more  
7 detailed guidance, or, in some cases, regulations out  
8 there for you to follow.

9           You got to obey the law as it is currently  
10 written. Nothing in this guidance document is  
11 intended to circumvent that requirement on you.

12           And for example, even on a farm operation,  
13 a packing house often might qualify as food  
14 establishments under the Food, Drug and Cosmetic Act,  
15 under FDA, and in that case, they should be following  
16 the good manufacturing practices contained in Title  
17 21 of the Code of Federal Regulations, Part 110.

18           In some cases, there are already  
19 regulations out there applicable to certain parts of  
20 your operation. You are going to be expected to  
21 follow them.

22           Once again, I hate repetition, but it is  
23 one way to fill up two and one-half hours. There are  
24 common potential vectors for pathogens for all fresh  
25 produce, such as water and manure. The broad-scope  
26 document is attempting to identify them, but we do

1 recognize there is an enormous range of  
2 farm-size-available water sources.

3 If you are already drawing your water from  
4 the river, and that's the only thing available to  
5 you, you don't have many options frequently; climatic  
6 and soil differences, climatic, this story that I  
7 told you about -- limits on some of our  
8 recommendations in -- on manure use that might apply  
9 in colder climates, fertilizer sources, employee  
10 availability, farm practices.

11 It's not intended to be one-size-fits-all.  
12 You are supposed to read it critically and see where  
13 you can apply it. Cultural practices may vary and  
14 the bottom bullet is what we want you to think about  
15 and comment on:

16 How can we best provide practical, concrete  
17 advice to growers that will move us toward safer  
18 produce without -- or at least keep produce as safe  
19 as it is in this world of emerging packagings,  
20 without being unnecessarily costly to growers?

21 That is the key question. Keep that in  
22 mind until you get to an open mike.

23 Now, some of the specific guidance in the  
24 draft document you have in front of you, once again,  
25 you saw the template: Water, manure, hygiene, both  
26 field, facility and worker, and transportation.



1           Some of our comments on water: Once again,  
2 the devil is in the details, you have to read the  
3 document to get the details.

4           Water is a concern in two aspects. Water  
5 which is contaminated itself is an inherent source of  
6 contamination, but even in clean water, if used  
7 improperly, if you don't think about how you use it,  
8 could be a vehicle for spreading pathogens, that  
9 might be localized and spotty, in the produce  
10 throughout a harvest in either the field, during the  
11 harvest or in the packing house.

12           So even good water could be a problem if  
13 used improperly.

14           These are just a list of some of the  
15 pathogens that water has been found to contain. I  
16 believe all of them have been associated with some  
17 illness out-break, although not necessarily -- well,  
18 I shouldn't say absolutely. Not all of them are  
19 associated with fresh produce, but it's some of the  
20 concerns we have with water.

21           Because of water's potential as a source of  
22 pathogenic microorganisms, growers should carefully  
23 analyze practices involving water and seek to limit  
24 the possibility of waterborne contamination. Well,  
25 easier said than done.

26           We realize that, but this is the key

1 thought behind what we want to say. Recognize the  
2 potential for water source to contain pathogens.  
3 Remember that that is a problem.

4 Sometimes it's a problem you can do  
5 something about because you might have options.  
6 Frequently -- or sometimes it may not be, but you  
7 should always be thinking about pathogens and your  
8 water source as a potential for adding unnecessary  
9 microbiological load to fresh produce.

10 The second bullet is also very interesting.  
11 Water should be of sufficient quality for its  
12 intended use and don't bother to look in the document  
13 for what "sufficient quality" is. We don't define  
14 it. We would be interested in thoughts and comments  
15 on what that would be.

16 Identify the source of water itself in  
17 different operations. This will vary with use and  
18 should be tailored to the needs of a particular  
19 operation.

20 The closer your product gets to the  
21 consumer, through various steps in a packing house,  
22 during harvest, the better, hopefully. You should be  
23 more concerned about the quality of the water you are  
24 using.

25 You should always be concerned about it,  
26 but it becomes more critical -- the most critical

1 thing will be the final wash before you package it  
2 and put it on the truck. That should be the best  
3 water you have, and once again, the guidance does not  
4 preempt any applicable Federal, State or local  
5 regulations.

6 Among the things we want you to consider,  
7 according to the guidance, identify and review the  
8 source of water used on the farm. As the degree of  
9 water to produce contact increases, so does the need  
10 for good quality water. The more the water is in  
11 direct contact with the produce, the more likely it  
12 is to leave some of these microbial pathogens of  
13 concern behind. Common sense. But sometimes  
14 difficult to deal with.

15 Your review may include determining whether  
16 the source of the water is from a well, open canal,  
17 reservoir, reused irrigation water, a municipality or  
18 other sources.

19 In each case, there might be different  
20 options available to you to better ensure the quality  
21 of your water. Once again, some further suggestions  
22 I'll give in the guidance document.

23 Controls may include many options such as  
24 delaying water use until water quality improves.  
25 Well, you know, if your crops have to be harvested,  
26 if -- or irrigated, you really can't delay that.

1           In some cases, it might be an option  
2 available to you, but, you know, you got to grow your  
3 crops. You got to get them to market. You got to  
4 wash them for packing.

5           But it is one option suggested in there.

6           Water treatment is another option if you  
7 have a high microbial load in your water source.

8           Alternative application methods that avoid  
9 water-to-produce contact.

10          Let's remember, the more the contact, the  
11 more the likelihood of spreading contamination and  
12 maintaining alternative water supplies.

13          The feasibility of these or other controls  
14 will depend on the intended water use and the needs  
15 and resources of a particular operation.

16          Once again, if you've only got one water  
17 supply, that's what you have to deal with. Your  
18 options become limited. We realize that.

19          A few little thoughts about irrigation  
20 water. Many factors influence a grower's choice of  
21 irrigation. You can now mix the water economics,  
22 water availabilities. Depending on the crop growers,  
23 you may need to consider using water delivery systems  
24 such as drip irrigation that minimize direct  
25 water-to-produce contact for certain produce.

26          It's a good comment. It may be applicable

1 for some crops. Among the comments we've been  
2 getting, at other meetings, is the cost of  
3 introducing a drip irrigation system, depending on  
4 the type of crop, and the amount of land involved.  
5 This is some of the things we've heard, I think, both  
6 in Grand Rapids and in New York.

7 You should also be aware of the use of crop  
8 protection sprays, and the feasibility of them as a  
9 mode for transmitting microbial contamination  
10 contained in water to produce.

11 Water used to mix and load pesticide sprays  
12 should be considered a potential source for  
13 pathogens.

14 It is interesting to note that we have  
15 never really solved absolutely the problem of  
16 Cyclospora associated with Guatemalan raspberries,  
17 but among the items of possible causes of the problem  
18 brought back by some of the CDC and FDA researchers  
19 that went down there is the fact that, in order to  
20 protect their well water source from chemicals and  
21 perhaps back-flow in mixing crop protection  
22 someplace, they go down to the local river when they  
23 were preparing their spray for fungicides and  
24 pesticides, and they use that water, which was  
25 nowhere near as good as the well water.

26 Something that they are not aware of, and,

1     you know, we want everyone else to be aware of, too.

2             Wash water, safe and sanitary water is  
3 recommended for use in washing produce in the field  
4 and in the packing environment.

5             Let's remember, washing is one of the  
6 things that helps remove dirt, and dirt which might  
7 contain these pathogens from the produce, but, once  
8 again, if done improperly, if the water source is  
9 contaminated or if the washing procedure is not  
10 adequately controlled, water might do nothing more  
11 but spread localized contamination through the  
12 produce.

13            Wash water, even with sanitizers, may  
14 reduce but not eliminate, pathogens on the surface of  
15 the produce. If pathogens are internalized, which in  
16 some cases they can be, washing has even less effect.

17            Among the comments we received when we  
18 talked about this, once again, we put them all on the  
19 table, I believe there is a recommendation in there  
20 that, for certain produce, the water used to wash  
21 should be ten degrees warmer than the produce because  
22 of the possibility of internalizing pathogens.

23            Many people, you know, at some of the  
24 meetings saying, uh, you know the idea, "One of the  
25 reasons we wash is to get the heat out of the product  
26 and help preserve the product and cool it down

1 quickly. And what you are doing is, you are inviting  
2 us to increase rot and degradation of our product by  
3 doing this."

4 It's one of the comments we have already  
5 received. Any other thoughts on that, we want to  
6 hear them.

7 If pathogens are not removed through  
8 inactivity, they can spread so that a significant  
9 proportion of the produce is contaminated, instead of  
10 sporadic item.

11 Once again, if you are going to wash, you  
12 have to think about what you are doing to it the best  
13 way possible. Don't spread localized contamination.

14 We mentioned chlorine as a potential water  
15 treatment to -- as one of the ways to do a better  
16 water wash and kill microorganisms. It's discussed  
17 fully under the wash water section of the document.

18 Cooling operations.

19 Water and ice used in cooling should be  
20 considered a potential source of contamination.

21 Any time water comes in contact with the  
22 product, it has a potential for adding or spreading  
23 contamination. That is the key point in almost  
24 everything we're talking about here with water.

25 Growers should be aware of water source  
26 used to make ice and follow practices to reduce the

1 risk of contamination during cooling operations.

2 The final thought I was asked to put on the  
3 board as we talk about water is, remember, even good  
4 water can be a problem. Water can be a vehicle for  
5 spreading localized contamination.

6 So even if you have a good water source,  
7 it's not a sterile world. Some of the product may be  
8 contaminated through natural causes, and if you don't  
9 wash it and control wash water properly, you might be  
10 spreading your problem rather than solving it, even  
11 with the use of good water.

12 Manure and municipal sludges.

13 Some of the thoughts in the guidance  
14 document under this section: Health officials and  
15 scientists agree that animal manure and human fecal  
16 matter represent a significant source of human  
17 pathogens. Most of the diseases we are talking about  
18 here are transmitted through the fecal-oral route.

19 So this is really key to control.

20 The use of manure or municipal sewage  
21 sludge in the production of produce must be closely  
22 managed to limit the potential for pathogen  
23 contamination of produce.

24 Growers must also be alert to the  
25 presence of human or animal fecal matter that  
26 may be unwittingly introduced into the



1 produce-growing-and-handling environment.

2 What we're talking about there is control  
3 in the fields of wild animals and water fowl.

4 This also generates a great deal of heated  
5 discussion as some of our grass-roots meetings. One  
6 of the questions I believe I received was, "Do you  
7 know what it costs to put up a deer fence around 40  
8 acres of land?"

9 And, of course, I had no idea, but perhaps  
10 you do, and would want to add more on that.

11 Properly treated manure or municipal sewage  
12 sludge can be an effective and safe fertilizer.  
13 Untreated or improperly treated manure or sludge used  
14 as a fertilizer to improve soil structure or that  
15 enters surface waters through run-off may contain  
16 pathogens that may contaminate your product.

17 So you got to be thinking about the use.  
18 You got to remember it's not just going to improve  
19 your yield. It's not going to only be good. There  
20 are potential problems here. You gotta think about  
21 the use. That's all we're asking you to do.

22 We realize municipal sewage sludge is not  
23 widely used on growing fresh produce. But if  
24 properly treated, there are some studies out there  
25 that shows it can be beneficial. That's why we  
26 mention it in the document.

1           What are the sources of fecal contamination  
2 most likely to involve produce?

3           We believe they are, the use of untreated  
4 or improperly treated manure, nearby composting or  
5 treatment operations, run-off, wind spread from an  
6 operation of composting or manure pile that is not  
7 properly controlled, nearby livestock or poultry  
8 operations.

9           All things you should be aware of. Nearby  
10 municipal waste water storage or disposal areas and  
11 high concentrations of wildlife in growing areas.

12           Growers may need to develop and follow good  
13 agricultural practices for handling manure to reduce  
14 the potential of introducing microbial hazards to  
15 produce.

16           Practices may include: Processes, such as  
17 composting -- we are going to talk a great deal about  
18 composting in the document -- to reduce possible  
19 levels of pathogens in manure. Minimizing to the  
20 extent feasible, direct or indirect manure to produce  
21 contact, especially close to harvest.

22           As with water, the closer your produce gets  
23 to the consumer's table, the more care and concern  
24 you as responsible growers should apply to your  
25 operation. Assessing adjacent and nearby land uses  
26 to determine risks from animals that may shed

1 pathogens that can cause contamination.

2           There are a number of ways we realize to  
3 treat manure to reduce pathogens. There is an  
4 extensive list discussed in the document, but the one  
5 we talk about most is composting, and composting  
6 refers to a managed process in which organic  
7 materials are digested aerobically or anaerobically  
8 by microbial action. Properly composted manure can  
9 be an effective and safe fertilizer and/or soil  
10 amendment.

11           One of the areas where we specify in the  
12 document that research is needed is in composting.  
13 While FDA and USDA do not now have sufficient data to  
14 make specific time and temperature recommendations  
15 that would apply to all composting or other manure  
16 treatment operations, good agricultural practices may  
17 reduce the risk of microbial cross-contamination from  
18 manure to fresh produce.

19           We don't -- we suggest you work through  
20 Extension and State agencies for the best advice  
21 currently available, what advice we believe -- is  
22 supportable is in the document.

23           Now talk about -- in the guidance document,  
24 we talk about GAPs for both treated and untreated  
25 manure will vary.

26           Untreated manure.

1           Here is the one that got me into a great  
2 deal of trouble in New York State, the idea being,  
3 reduce contact of the produce with the untreated  
4 manure, as it gets closer and closer to harvest, by  
5 maximizing the time between application and harvest.

6           Recommended minimums generally range from  
7 40 to 60 days before harvest. Some recommendation  
8 are 120 days or longer.

9           What they told us is, "Well, 120 days is a  
10 bit beyond our growing season. If we do it in the  
11 fall, you get problems with run-off and perhaps  
12 contamination of water sources in that way."

13           The treated manure, the natural fertilizer,  
14 such as composted manure, may need to be produced in  
15 a manner to reduce the likelihood of introducing  
16 microbial hazards.

17           Once again, what advice that good science  
18 can give is we believe in the document, we believe  
19 more research is needed.

20           Care should be taken to avoid  
21 cross-contamination of fresh produce from manure that  
22 is in the process of being composted or otherwise  
23 treated. Common sense, you know: Don't put it on  
24 the uphill slope from the field where you are growing  
25 your produce.

26           Likewise, improperly treated or

1       incompletely treated manure may also -- may itself be  
2       a source of contamination.

3               Composting and other treatments may reduce,  
4       but might not eliminate, pathogens in manure. Here  
5       is another place where further research is necessary.

6               Furthermore, it is unknown to what extent  
7       pathogens that survive treatment may regrow in  
8       composted manure that is stored before use.

9               Therefore, what we recommend in the  
10       document, to the extent feasible, growers using  
11       treated manure may want to consider some of the  
12       recommendations made for untreated manure, such as  
13       maximizing time between application and harvest.

14               In handling manure, we give -- obviously,  
15       we just try to point out some of the things that  
16       could go wrong. Secure the manure or compost to  
17       prevent cross-contamination from run-off.

18               Once again, it should be somehow secured,  
19       probably not uphill from your growing fields; secure  
20       it to prevent leaching into the soil and wind spread.

21               The next major component of the document  
22       is --

23               Do you want to keep going?

24               MR. NELSON: It's 10:30. Do you want to  
25       take a break?

26               MR. LOWELL: I'd appreciate it.

1 MR. NELSON: Okay. Give them 15. Let's  
2 take a 15-minute break, and please be back by quarter  
3 'til.

4 (A break was taken between 10:30 and  
5 10:45 a.m.)

6 MR. GARDINE: If you would please settle  
7 down. The important thing is to hear from you, and  
8 we would like to get to that as quickly as we can.  
9 We were about to start talking about sanitation and  
10 hygiene.

11 As a beginning point here, among the  
12 comments we were constantly receiving, wherever we  
13 went, was the way this is reading, "You are imposing  
14 a burden on the grower to be concerned and to take  
15 some responsibility for the health and the hygiene of  
16 their worker."

17 The answer to that is, Yes, the way it is  
18 written now, the document is doing that.

19 But beyond that, I just want to stress that  
20 this is no different -- these points are no different  
21 than what FDA says for retail for food handlers, in  
22 general, and this is something that is something that  
23 will go directly to the consumers table, without any  
24 processing to remove microbial load.

25 So, as public health officials, I have to  
26 say, I certainly feel kind of strongly about this, if

1     there are -- if the same concern is held here about  
2     the responsibility and the need for the grower to be  
3     aware of some of the things we talked about here,  
4     please bear that in mind.

5             It's no different than what we ask a person  
6     running a restaurant to consider in controlling  
7     workers, and what might the options be, and how can  
8     we, in attempting to ignore microbial load on fresh  
9     produce, ignore something like this?

10            Worker health and hygiene play a critical  
11     role in the controls to minimize microbial  
12     contamination of fresh produce.

13            Fecal-oral disease are the primary --  
14     primary microbial concern. All of the diseases we  
15     are concerned with here are generally through the  
16     fecal-oral route.

17            To control potential hazards, personal  
18     health, good hygienic practices by all workers are  
19     essential in the control of microbial hazards.

20            Infectious disease, ill health with  
21     diarrhea, open lesions, and so forth, are a source of  
22     microbial contamination and can be transmitted to  
23     produce.

24            Among the recommendations we make,  
25     employees should report, to the person in charge, any  
26     information about their health or activities as they

1 relate to diseases transmissible through food.

2 Well, we hear from growers in other parts  
3 of the country, "Well, yeah, that means we're not  
4 going to pay them. The first time we don't pay them,  
5 we are going to stop hearing these reports."

6 Still, can we appropriately ignore this as  
7 a source of contamination of food?

8 Are there other things -- are there other  
9 ways we could phrase this in the document, i.e.,  
10 encourage, where possible, that the worker drive the  
11 truck that day, or where possible, be assigned on  
12 other duties?

13 I realize that there is only so much type  
14 of work that needs to be done, and when you are  
15 harvesting, you need harvesters, but think about  
16 options. This is something that's going to be very  
17 difficult for us to turn our back to.

18 Here is a key thing of concern: The person  
19 in charge should monitor, we say, the health of  
20 employees. Individuals with diarrheal disease should  
21 not work with fresh produce.

22 Once again, very similar to what we say to  
23 people handling food on the retail level, something  
24 we feel strongly about, something I think most public  
25 health officials in this country would agree with,  
26 but difficult to do, but in a guidance document,



1     should we not at least make the point and find ways  
2     to work toward that goal?

3             All employees who are involved in the  
4     harvesting, packing and distribution of fresh produce  
5     should be trained in good hygienic practices. Don't  
6     think they know how to wash their hands properly.

7             Consider establishing a training program.  
8     It doesn't have to be grower-specific. Perhaps it  
9     could be a County program. Perhaps it could be an  
10    industry or valley program, but something like that  
11    should be considered and the program should  
12    include -- might include a system to monitor and  
13    evaluate compliance with the program.

14            The employees should be taught proper hand  
15    washing techniques, use of sanitation facilities,  
16    such as on-site latrines, and avoiding the  
17    elimination of wastes outside of these facilities  
18    should be encouraged.

19            If I were the drafter, I would say "must be  
20    encouraged," which is a personal opinion, but it is  
21    guidance.

22            In the field, some of the things -- some of  
23    the recommendations we give about what's happening  
24    out in the field:

25            The proximity of toilet facilities, one of  
26    the key things.

1 Remember: Fecal-oral route, transmission.  
2 The proximity and accessibility of facilities to  
3 harvest crews in all sectors of fresh produce  
4 production is important.

5 Folks ain't going to use it if it ain't  
6 there, or if it's too far away. Workers should have  
7 the opportunity to use facilities when needed, not  
8 only when they are on break.

9 This will help reduce the incidence of  
10 workers relieving themselves elsewhere. I will not  
11 go into that in great depth.

12 Assure that the location of facilities is  
13 not near a water source used in irrigation or in a  
14 location that would subject it to potential run-off  
15 in the event of heavy rains. Just as you would  
16 control a manure pile to prevent contaminating the  
17 fields, you should do the same with port-a-potty.

18 Adequate hand washing stations should be  
19 made available. This -- we are talking about  
20 basically facilities itself both in the field -- and  
21 all this applies, I should say, to both a facility  
22 such as a packing house and the field.

23 Toilet facilities should be well supplied  
24 with the usual, and maintained in sanitary condition  
25 and in good repair at all times.

26 Things we ask you to consider in the

1 guidance document: Clean or service portable toilets  
2 away from the field, if possible.

3 Once again, we are trying to avoid  
4 contamination of the food with fecal matter -- with  
5 untreated fecal matter.

6 Dispose wastes through a sub-surface septic  
7 tank system, if possible. Drain waste water away  
8 from the field, probably, always, or collect it in a  
9 drainage tank to be correctly disposed of at a remote  
10 site.

11 In harvesting your crop, one of the things  
12 that is suggested is that you remove as much dirt and  
13 mud as possible from the produce while in the field.  
14 Why?

15 Even if you wash it in the packing house,  
16 why carry that dirt?

17 Dirt is a source of contamination. Clean  
18 as much of it in the field as possible. It's going  
19 to be more effective and less likely to spread  
20 pathogens once you get the product to the packing  
21 house.

22 Something you can control, damaged or muddy  
23 cartons, should be repaired, cleaned or discarded in  
24 an effort to reduce microbial contamination of fresh  
25 produce.

26 Don't put the product in dirty packing,

1 even if it's just packaging to take it from the field  
2 to the packing house. Even if it's just that crate.

3 Care is needed to ensure that produce that  
4 is packaged in the field is not contaminated in the  
5 process. And we recommend that inspectors, buyers,  
6 visitors, wash their hands or wear clean, disposable  
7 gloves before inspecting produce.

8 Early on in the document, there was a lot  
9 of talk about suggesting use of gloves in packing  
10 houses and whenever handling the document.

11 We heard that that was impractical. But we  
12 do demand that hands be washed, or the document gives  
13 guidance that the hands be washed.

14 Certainly, in other things like our food  
15 code, that is clearly gone over, but when you are  
16 having people come in and visit that are going to be  
17 touching the produce, not as part of the production  
18 where they need that manipulation, make sure they  
19 wash their hands or wear gloves.

20 Equipment maintenance. We're talking here  
21 about equipment in harvesting in the field. There  
22 should be a person in charge of maintaining the  
23 equipment sanitation, and know what the equipment is  
24 used for.

25 It is inappropriate, for example, to use  
26 the same truck to haul manure and product, cleaning

1 it, to use it to pack your harvested crop to bring it  
2 to a packing or cooling house, you are just adding  
3 microbial load.

4 Someone should know what the equipment is  
5 used for and maintain it in clean condition  
6 appropriate for its use. Keep the equipment as clean  
7 as possible. We realize you are in the field. We're  
8 not talking about sparkling here.

9 Items such as lunches, if you will, tools,  
10 should not be carried on harvesting equipment, and  
11 remove contaminants, mud, diesel, grease, et cetera,  
12 from equipment daily. Anything that would add to  
13 your microbial load that you can control reasonably.

14 Anything.

15 And we're now in the packing house facility  
16 -- anything in the process from harvest to  
17 processing that makes contact with produce has the  
18 potential to contaminate it.

19 The bottom line is, what we've been talking  
20 about all day is, poor sanitation in the packing  
21 house can increase the risk of contamination of  
22 produce and water supplies used with produce.

23 Once again, nothing we say in this guidance  
24 document eliminates the need to comply with other  
25 applicable, local, State or Federal regulations.

26 We also refer you to the general Code of

1 Federal Regulations, entitled Code of Federal  
2 Regulations 21 -- Code of Federal Regulations, Part  
3 110.20.

4 The same as in the field of -- but in the  
5 packing house, certainly more care should be taken,  
6 because, once again, you are getting closer to the  
7 consumer's table, equipment should be kept clean and  
8 defective equipment removed as appropriate.

9 Equipment should not be used  
10 inappropriately and not for its intended use.

11 Keep the packing house and cooling  
12 facilities clean and sanitary.

13 Talk about pest control. Obviously, once  
14 you are in the packing house, there are -- this  
15 starts to become more of a concern. All animals are  
16 potential sources of contamination.

17 In enclosed facilities, a pest control  
18 program is essential to limit the contamination from  
19 pests. Packing house, processing facilities and  
20 grounds around them should be in good condition to  
21 protect from pest contamination inside.

22 I think it is the enclosed packing house is  
23 probably the only place in the guidance where we talk  
24 about suggesting record keeping and we talk about --  
25 we suggest maintaining a pest control log to make  
26 sure that you are keeping control of something that

1 is controllable in an enclosed packing house.

2 The final part of the document that we  
3 believe might have some final control, or part of  
4 your operation that we believe might have some  
5 universal applicability in adding microbial pathogens  
6 to produce, is transportation.

7 Contamination of produce may occur due to  
8 improper practices during handling, loading,  
9 unloading and transportation operations.

10 Transportation, whether from the field to  
11 the packing house, from the packing house to your  
12 purchaser, is something you should be concerned  
13 about. Wherever produce is transported, the  
14 sanitation conditions should be evaluated, especially  
15 between links in the distribution chain.

16 Cross-contamination from other foods and  
17 non-food sources and contaminated surfaces may occur  
18 during transport.

19 Segregate fresh produce from other food and  
20 non-food sources of pathogens in order to prevent  
21 contamination of the produce.

22 What we're concerned about here is, you put  
23 it on the truck, what's going to happen to it?

24 Try to assure that instruction or other  
25 carrier sanitation requirements are met before  
26 loading produce.

1           Remember, we're talking about produce here.  
2   It is not a sterile product. Everything we're  
3   talking about, up 'til now, is reducing microbial  
4   load. We don't expect the truck to be sterile, but it  
5   should be clean.

6           And depending on its previous use, if that  
7   can be determined, maybe it should have been  
8   sterilized before we put produce in it? What was it  
9   used to haul before your product got on it?

10          Keep open communication along the  
11   transportation route regarding food safety risks and  
12   the need for adequate safety steps.

13          Hey, you should be talking to the people  
14   transporting your product. Let them know what the  
15   concerns are with transporting fresh produce, and  
16   what they should be aware of and what you expect of  
17   them.

18          There is a final part of this document that  
19   has nothing to do with reducing microbial load. And  
20   that is the section on what is up here is trace-back,  
21   but it's really positive lot identification.

22          It is something we put there to encourage  
23   industry to consider and see where it's applicable.  
24   We're talking about where can we code the product to  
25   enable you, State authorities, local authorities and  
26   Federal authorities, should there be an out-break, to



1 trace it back to its source.

2 We think this is something you should  
3 consider because it's good for you, it's good for us,  
4 it's good for the health of the consumer.

5 Positive lot identification for produce, we  
6 believe, is necessary because fresh produce will  
7 never be free of contaminants. As is said many, many  
8 times, we're talking about reducing and controlling  
9 microbial load on fresh produce. Until other  
10 research and other control steps are found, you can't  
11 eliminate it.

12 Trace-backs won't prevent a hazard, but it  
13 could, if done properly, limit the potential scope of  
14 the out-break if health authorities can focus in on  
15 something very quickly. Limit populations at risk.  
16 Lead to specific company source or growing field, as  
17 opposed to the entire avocado industry. Well, the  
18 person implicated is Joe's -- you know, Joe's farm.

19 It will lessen the economic burden on  
20 operators not responsible for the problem, and we  
21 realize, of course, that, depending on how the fruit  
22 or vegetables are marketed, this is more easily  
23 implemented for some commodities than others,  
24 depending on how they are packaged, or are they  
25 displayed in bulk, because that's what people like to  
26 see, is nice, ripe fruit and colorful vegetables when

1       they walk into a produce market.

2               But we're suggesting you do what you can.  
3       Make sure that your packages, when they leave your  
4       farm, are adequately identified, and we will be  
5       working with the retail industry to encourage  
6       maintaining that as far down the chain as we possibly  
7       can.

8               Trace-backs minimizes -- now, from -- as  
9       public health officials, we, the State authorities,  
10      the local authorities, CDC, trace-backs would  
11      minimize the unnecessary expenditure of public health  
12      risks. If a package is adequately coded or properly  
13      identified, we could focus in on where the risk is  
14      most likely to have occurred as quickly as possible.  
15      It will reduce the anxiety of the consumer. It frees  
16      consumers to enjoy fruits and vegetables not  
17      implicated in the out-break.

18              I'll repeat again, the Federal Government,  
19      State and local authorities are saying, "Eat fresh  
20      fruits and vegetables."

21              Why? Because it's good for you.

22              We are encouraging people to do this and we  
23      don't want anything that will pull them back from  
24      consuming this very nutritious and very wise life  
25      choice for them. Outbreaks of this nature do that.

26              We want you to consider your current

1 procedures for positive lot identification, and if  
2 possible, develop procedures that you control as far  
3 down the distribution chain as possible.

4 You may have to work with the people that  
5 you are supplying and see what you can come up with  
6 together.

7 Here are some -- this is -- I'm not going  
8 to go into this in great detail. It is contained in  
9 the document. Some suggestions on what would be the  
10 most effective type trace-back, for us and I'm going  
11 to shut this off now, and if someone would just shut  
12 the projector, one other story.

13 And for those of you who have been to the  
14 other presentations, you are going to have to hear  
15 this story again, and it's very true, and I tell it  
16 now because I think it helps identify why we want --  
17 we encourage positive lot identification, and why  
18 this whole episode -- this whole initiative on the  
19 part of the President is ongoing.

20 Those of you in California probably  
21 remember the Hepatitis A in processed strawberry  
22 incidents of this year.

23 We at FDA know that we do not know if it  
24 was the fresh strawberries from Mexico. We do not  
25 know if the problem occurred in the packing house.  
26 We do not know if the contamination occurred in the

1 food handling. That was never identified. This was  
2 never stated by Federal authorities, certainly not  
3 State authorities. It may have been misquoted  
4 somewhere locally, as being absolutely a cause --  
5 caused this illness outbreak in the schools -- and I  
6 believe it was Minnesota? --

7 VOICES: Michigan.

8 MR. GARDINE: -- Michigan? I got the "M"  
9 right -- as being due to the fresh strawberries that  
10 were imported from Mexico, then processed in the  
11 United States, and then served in the school lunch  
12 program.

13 But that week, when that story was breaking  
14 and making the national news, I got a call in my  
15 office, which, as you heard at the introduction is  
16 the Division of Import Operations.

17 We pride ourselves, or like to pride  
18 ourselves, sometimes we meet this criteria for  
19 ourselves -- in Customer Service.

20 Our customers are the local FDA offices who  
21 are doing import work primarily, but also the  
22 importers, because when they have problems, they come  
23 to us, and we have to either tell them that our  
24 district is right, or work with them to see what  
25 corrections we can make if we think we mis-spoke.

26 I got a call from an importer calling on a

1 totally different matter.' I was real busy that day.  
2 It was a bad day. I think we had another problem  
3 ongoing because, quite frankly, since we never  
4 identified Mexican strawberries as the cause, this  
5 was something my office was tracking, but not  
6 actively involved in, not getting great guidance out,  
7 certainly.

8 We never put Mexican strawberries on any  
9 sort of detention without examination because they  
10 were never clearly implicated in the product. But I  
11 get a call from this importer, I forget what he was  
12 calling about, but I wasn't there. He called in the  
13 early morning. I couldn't return his call until 4:00  
14 or 4:30 that afternoon.

15 I felt kind of bad and I start by saying,  
16 sir, you know, "Mr. so-and-so, I'm real sorry. It's  
17 late and it's been a really bad day. Actually it's  
18 been a bad week," and this guy -- he is quiet at the  
19 other end of the phone, and then there is laughter,  
20 and he says to me, "I'm one of the biggest importers  
21 of strawberries from Mexico, and you think you are  
22 having a bad week."

23 He said he had nothing to do with supplying  
24 the plant in California. He claimed that his fields  
25 were actually in a different part of the country and  
26 he claimed, I'm sure with some exaggeration, that he

1 was having a problem giving his product away right  
2 now.

3 These incidents hurt us all. They hurt the  
4 American people. Of course, it denies them a sound  
5 and nutritious and encouraged source of food. It  
6 hurts the producer.

7 It is difficult for public health officials  
8 to get a handle on, and what we want to work with, in  
9 industry, States, local authorities, academia on, is  
10 getting the best guidance out so I don't have to take  
11 calls like this, and you, to extent possible, never  
12 have to deal -- if the guidance is good, it will  
13 limit your exposure to dealing with incidents like  
14 that.

15 Thank you all for your kind attention.

16 Now I think it's open mike, for any  
17 thoughts or questions of clarification on the  
18 guidance document.

19 Please, somebody? I would ask you to come  
20 to one of the mikes and introduce yourself.

21 Yes?

22 MS. RUSSELL: My name is Carol Russell, and  
23 I represent Pacific International Marketing. I just  
24 had a question. I was looking through some of the  
25 other paperwork. I think that I recognized that  
26 every step of the way is important and you are

1 talking about numbers when you're talking about --  
2 reducing microbial incidents in general.

3 It seems to me that the consumer is a  
4 hugely important link in making sure this is done,  
5 and I know there was comment about education to the  
6 consumer, but isn't it of benefit to everyone to make  
7 sure the consumer understands, as well as every step  
8 along the way with the produce?

9 MR. GARDINE: Yes. We -- there is a  
10 consumer education program. We're gearing up right  
11 now. I believe it's "Fight-bac", B-A-C, for  
12 bacteria.

13 It's a consumer education program. I think  
14 in some of your handouts, the FDA hand out, I think  
15 it contained some of the literature we're creating to  
16 outreach to the consumer. The consumer is a critical  
17 link in the food protection chain, and let's remember  
18 what the President's initiative is, "from farm to  
19 table."

20 The consumer touches it before it gets onto  
21 the table and handles the product. We do realize  
22 that, and that is a very important part of what we  
23 will be trying to do.

24 MS. DODGE: My name is Elaine Dodge. I'm  
25 with "STOP," "Safe Table is Our Priority."

26 I have three questions, so I can ask three

1 in a row, or I can --

2 MR. GARDINE: How about -- yeah, three in a  
3 row, but we might have to repeat them, I think.

4 MS. DODGE: The first question speaks to  
5 the premise of the guidance document, and I'm not  
6 really sure why the FDA and USDA are the appropriate  
7 people to answer it, but my question is, what was in  
8 the President's thinking, or whoever it was who  
9 drafted this guidance document, that it in fact  
10 should be a guidance document, rather than a  
11 regulatory document, that, of course, being that  
12 all of us are most familiar with your capacity as  
13 regulators, rather than generators of  
14 recommendations.

15 My second question is, in response to what  
16 Dr. Breitmeyer said from the California Department of  
17 Agriculture, requesting that certain products not be  
18 identified or specified in the guidance document, so  
19 the consumers didn't draw an incorrect conclusion  
20 that they should be worried about some products.

21 My question is, three weeks ago, I was in  
22 Sacramento, and there was a series of epidemiologists  
23 who came forward and gave presentations on certain  
24 products that are in fact associated with outbreaks,  
25 and so I don't understand why it wouldn't be to  
26 everyone's benefit, particularly consumers, because



1 consumers are, you know, sort of the last critical  
2 control point for their own self-protection, why they  
3 shouldn't know which products are associated with  
4 risks, as opposed to ones that haven't been.

5 And then, my final question -- which you  
6 may be exactly the right person to answer it -- is,  
7 I -- it's repeated throughout the guidance document,  
8 a phrase about accounting for "specific commodity  
9 cultural and regional differences," and I really  
10 don't understand what that means, and I'm hoping you  
11 can give me some examples.

12 MR. GARDINE: To begin, and I think John  
13 Vanderveen may want to talk about this, why guidance  
14 and not a regulation?

15 Number 1, we do not believe that the  
16 science is yet there to support making this a  
17 regulation.

18 Number 2, we do not believe that -- yet  
19 that there is an absolute need for this as a  
20 regulation in order to effect what we want to effect,  
21 i.e., improved practices to minimize microbial  
22 health.

23 So basically, Number 1, in some areas, the  
24 need for additional science because, you notice, in  
25 this document, there are very few numbers. There are  
26 very few things about what to tell people to check

1 for in the water. There is a lot, lot of research  
2 that must be done.

3 But Number 2, in all honesty, we see this  
4 as something good for the grower. We believe this is  
5 something that the industry in the U.S., as their  
6 practices -- as their efforts to develop their own  
7 good practice guidance has already indicated, is  
8 something that is necessary for the grower, that they  
9 are aware that they are going to have to do, we see  
10 these changes taking place and we believe that, by  
11 putting out this guidance, we can encourage these  
12 changes, to some extent.

13 That's my answer to Number 1.

14 Number 2, are not some products associated  
15 with outbreaks, and therefore would it not be  
16 appropriate to make specific guidance documents for  
17 specific commodities?

18 I don't know how to respond to that since  
19 that's an open question, so we'll just take that as  
20 your comment on that.

21 And Number 3, if recollection serves, there  
22 is a statement about specific cultural and growing  
23 practices.

24 What we're trying to get to there is that  
25 it is very difficult to talk about one-size-fits-all  
26 in agriculture. I think the story I gave about the

1 growing season in the northeast is a prime example.  
2 We might talk about 120 days, and that might be  
3 applicable in Florida and Southern California and  
4 along in the valley in Texas near Brownsville, but it  
5 doesn't work in upstate New York because they don't  
6 have that kind of growing season.

7 Crops, depending upon the type of crop you  
8 are dealing with, the type of irrigation that is most  
9 effective for your crop, would vary.

10 For example, in some cases, flood  
11 irrigation, especially in -- when you are dealing  
12 with tree -- tree fruits, might be very appropriate  
13 to irrigate, but you damn as heck wouldn't want to do  
14 that with something like berries which would only  
15 result in mold and destruction of your product. You  
16 want to avoid water contact where possible.

17 So depending upon -- there is a great  
18 variation of what is doable, depending on crop, the  
19 growing conditions in the area, and that's why we do  
20 not believe this is a one-size-fits-all document, and  
21 must be tailored.

22 I do not know if I got to your third  
23 question or if I answered it adequately. John?

24 MR. VANDERVEEN: Yeah. I want to add to  
25 what has been said. I'm John Vanderveen,  
26 incidentally.

1 I think we are in a changing time. Years  
2 ago, I think that it was appropriate to do a lot more  
3 regulation than it is now.

4 Industry has grown significantly in this  
5 country. The diversity in the grocery store today,  
6 the amount of different products that are there are  
7 just overwhelming, in some cases.

8 You need to just go across the highway and  
9 take a look at that new grocery store over there and  
10 see the number of products -- the number of produce  
11 items in that grocery store, and realize that we're  
12 really talking about something that is  
13 extraordinarily broad at this point in time.

14 And this is not only true in Salinas, here,  
15 but it's true across the United States. You see  
16 grocery stores with this type of produce all year  
17 'round.

18 What's happening also is that we're  
19 downsizing, to some degree, in government. We have  
20 even less resources to go out and do what we  
21 traditionally did: Go and inspect and sample and do  
22 analysis, and so forth.

23 What we also learned, in reality, is that  
24 science tells us that, unless you do enormous amounts  
25 of sampling, you are not going to get the true  
26 picture.

1           The real thing that we've learned is that  
2 prevention is the best way to go about preventing  
3 disease -- to keep these foods safe.

4           You need to do things that's going to  
5 prevent the possibility that microorganisms are there  
6 that are harmful, and we're trying to approach it in  
7 that manner.

8           And the third thing that I want to say is  
9 the fact that government has come to the realization  
10 that partnerships are what's important, that we have  
11 to work with industry. We have to -- that's what  
12 HACCP is about.

13           We are not suggesting we are going to get  
14 into a HACCP program here, but what we're trying to  
15 do is work together, work to have the government,  
16 both Federal and State and local governments, work  
17 with industry.

18           If there is a real problem, of course,  
19 we're going to have to step in and take regulatory  
20 action, but we've got enough regulations on the books  
21 to take care of that type of thing.

22           What we want to do is work with industry  
23 and try to make sure that we are providing the right  
24 guidance, that everybody is talking the same way, in  
25 terms of this is the best that we can do, and then  
26 the second, and last point, is:

1           We're talking about a dynamic situation,  
2 something that's changing.

3           We have new processes coming in, very  
4 frequently nowadays, industry changes very, very  
5 rapidly, new equipment concepts, new agricultural  
6 practices, and what we want to do is be able to keep  
7 up with that.

8           And if you write regulations, it takes a  
9 very, very difficult time to try to keep up with  
10 technology. So guidance is a way in which we can do  
11 this, and I think that's the reason why we're not  
12 writing regulations.

13           MR. GARDINE: And let me just say, I'm very  
14 pleased you are here today, and in some of the other  
15 meetings, we did not have consumer groups, and I hope  
16 you will take this as an opportunity to perhaps  
17 engage in debate, if you think it's appropriate.

18           MR. NELSON: The next question?

19           MR. ISAACS: My name is Mark Isaacs. I'm  
20 from Sun Orchard, and I'm Chairman of the American  
21 Fresh Juice Council. This program seems to be on a  
22 fairly fast track, and no pun intended, and I was  
23 curious if that is based on risk-base analysis that  
24 was done, that prompted the President to have a focus  
25 like this.

26           And then, secondly, it's been made very

1 clear that this is a guide, and I'd like to  
2 understand what the FDA's expectations are, as  
3 relates to compliance, and how and what will be done  
4 to measure this compliance?

5 MR. GARDINE: All right. Me first.  
6 Regarding fast-truck and fast-track. That is  
7 questioned. I -- quite frankly, I cannot answer  
8 that. You have to speak to President Clinton's  
9 people as to what thoughts were going on, to generate  
10 this, but I will say, as a public health official who  
11 has spent much of the past two years dealing with  
12 Guatemalan raspberries, various other outbreaks, that  
13 this is not simply a perceived problem.

14 It is one that all of us have to try and  
15 get our hands around and help prevent for the  
16 future.

17 Whatever the President Clinton's reasons  
18 were, I am delighted that he initiated this, because  
19 these problems are going to be with us for quite some  
20 time, and we cannot blink at them. We should face  
21 them head on and try to do what we can to limit them.  
22 I think we have a concern.

23 Our food supply is safe, but there is a  
24 concern that things are changing. E. coli 0157:H7 is  
25 a terrible thing, and it's a relatively new pathogen.  
26 It's not something -- we believe it's not something

1 that was just -- that we could never detect it  
2 before.

3 We believe that this is a bug generated  
4 fairly new -- fairly recently. Because of that, if  
5 it happened once, it could happen again. We have to  
6 get, as a society, our hands around this. FDA's  
7 expectations -- and I think USDA expectations, if  
8 Dr. Gomez wants to comment on it, of use of guidance  
9 -- I think your question was what exactly were  
10 expectations from -- for enforcement?

11 You can't enforce guidance. You go to a  
12 court in front of a judge, he laughs at you and  
13 throws you out the door.

14 We are talking about education, outreach,  
15 jawboning, encouraging working with States, working  
16 with your trade associations for outreach. We've  
17 begun some of these conversations about the best way  
18 to do this, but it is very difficult to give you  
19 firmer details until we have the final guidance  
20 documents.

21 Very appropriately, for example, if I  
22 approach some trade organizations about, you know, do  
23 you think it's appropriate for you to work with us on  
24 outreach and education on this, they say, Well, let's  
25 wait until June or July, when we see a final document  
26 that you want us to outreach on, and see if we think



1       it's worth a damn.

2               So we have our -- our expectation is that  
3       this is going to be an educational effort, and  
4       nothing more. And -- but I should say, as strong an  
5       educational effort as we can make it.

6               MR. NELSON: Next question? No? Go ahead.

7               MR. STEARNS: Yeah. I'm Ken Stearns with  
8       Monterey Mushrooms. Just a couple of comments. It's  
9       apparent that the Federal government would like some  
10      help with composting operations. I suggest you go to  
11      the mushroom industry. We're compost experts and  
12      probably, like, American Mushroom Institute would be  
13      very happy to help you.

14              MR. GARDINE: Do you know personally  
15      whether they have specific guidance available that  
16      they share their members?

17              MR. STEARNS: Yeah, there is quite a bit of  
18      documentation out there. '

19              Secondly, I see there are no OSHA  
20      representatives here, because a lot of things -- you  
21      are talking about toilet facilities, it's not "should  
22      have" it available, but it's a "must."

23              And finally, I think, in this type of  
24      forum, it would also be good to talk a little bit  
25      more about the CFR 21-110, you know, the -- for food  
26      processors, because a lot of agricultural -- you know

1 processors, they don't know to follow these  
2 regulations, and I think this type of format is very  
3 important.

4 MR. GARDINE: In response, I, first of all  
5 want to thank you for the comment about the American  
6 Mushroom Institute. And I have a hunch our drafters  
7 will be contacting them relatively shortly.

8 I did point out, at, I think, the beginning  
9 that OSHA was involved in this, but it is a guidance  
10 document, and so we use OSHA, but remember, we  
11 reference all the time that it does not in any way  
12 eliminate the need to comply with existing Federal  
13 and State laws.

14 As for 21-110, thanks for the advice, our  
15 thoughts were you didn't want to hear from us any  
16 more than necessary. We were here to hear from you.  
17 We tagged out an hour of 21-110, but that kind of  
18 detracts from what we want -- from what we, as the  
19 drafters of this guidance, want from this meeting.  
20 We don't want to talk to you, as delightful as that  
21 is, but we want to hear from you about what we are  
22 considering here, but thanks for the advice. Perhaps  
23 we will in the future.

24 MR. NELSON: Next question? No questions?  
25 Dr. Breitmeyer?

26 MR. BREITMEYER: Richard Breitmeyer,

1 Department of Food and Agriculture. I would like to  
2 clarify a concern for selecting specific  
3 commodities. Our concern is that commodities not be  
4 selected for the wrong reasons.

5 It seemed arbitrary, in earlier  
6 discussions, to throw out that four commodities  
7 should be selected for '98 without any criteria for  
8 selecting those.

9 We think it's very appropriate to address  
10 these recommended guidelines for all commodities, not  
11 waiting for a problem to occur, but to put prevention  
12 practices in place to prevent all commodities that  
13 can become contaminated.

14 If a certain commodity is identified with  
15 appropriate scientific research with appropriate risk  
16 assessment as truly a risk in a ready-to-eat form,  
17 then it probably would be very appropriate to  
18 recommend specific guidelines, but make sure we have  
19 the right science and right risk assessment to make  
20 that decision.

21 MR. NELSON: Next question? Don't be  
22 bashful. Yes.

23 DR. ZAWEL: I am Stacey Zawel with the  
24 United Fresh Fruit and Vegetable Association.

25 Tom, your comment, just previous to this,  
26 regarding the -- how do you regulate using this

1 guidance, and that in fact you can't enforce a  
2 guidance, and that in a court of law, you would be  
3 laughed out of the room.

4 And, as a matter of fact, that isn't the  
5 case at all, and that's a big concern on behalf of  
6 the industry, not only for what you are doing, but  
7 for a lot of the volunteer efforts that have been  
8 undertaken.

9 As a matter of fact, in the industry-wide  
10 guidance to reduce microbiological issues, which you  
11 have seen, there is a statement that, "We do need  
12 increased information and new technologies to permit  
13 a better understanding of." --

14 (The spokesperson was requested to read  
15 more slowly.)

16 -- and this being the case, it states,  
17 "This document is not intended to establish and  
18 should not be construed as establishing industry  
19 standards imposing any legal obligation or providing  
20 any legal benefit," because, in a court of law, much  
21 to the contrary, you will be required to follow what  
22 the industry thinks are the best practices, and if  
23 you are not, you could in fact be found in violation  
24 of what your people think is the best idea.

25 And so it's a great concern for the  
26 industry in providing documentation.

1           However, we obviously think it's important,  
2           and it's going to be the same thing for this.

3           MR. GARDINE: Stacey, just for a moment,  
4           just for clarification, I realize that perhaps in a  
5           civil lawsuit someone could take your guidance, our  
6           guidance or any guidance document, and bring it into  
7           court.

8           But I think the point I was trying to make  
9           is that, as a traditional regulatory agency, with  
10          guidance, FDA is not going to be out on the farm  
11          saying, "Oop, you didn't do this, you didn't do that,  
12          therefore you know we're going to enjoin you with  
13          forced compliance."

14          We would not do that in a guidance. In  
15          that case, we would very likely be laughed out of  
16          court.

17          DR. ZAWEL: Yeah, I think that, you know,  
18          we've talked about this, or this has come up along  
19          the way.

20          MR. GARDINE: I just want to add, I do  
21          believe that was the intent of the gentleman's  
22          question.

23          "What is FDA going to do?"

24          DR. ZAWEL: Right, but it's also really  
25          important, and we've seen it in some other interests,  
26          where FDA has in fact enforced guidance and this

1 happened in the refrigeration labeling, and  
2 therefore, while that is the intention of guidance, I  
3 think that you, as the Federal FDA, and we've talked  
4 about this, need to be very, very careful in  
5 educating all of the local inspectors as to the  
6 definition of guidance versus regulation, and what  
7 that means and what they do.

8 MR. NELSON: Next question? Anyone else?  
9 Okay. If we don't have any more questions -- do you  
10 have a question back there?

11 Yes.

12 MS. GERREN: Donna Gerren with Boskovich  
13 Farms. There's been, you know, comments on not  
14 putting research together because there is not  
15 science to back it up, and not appropriate science to  
16 back it up.

17 Well, who is going to do the appropriate  
18 science and who is going to evaluate its  
19 appropriateness? I mean, whose responsibility is it,  
20 and who is going to fund that type of research?

21 MR. VANDERVEEN: Okay. There is a  
22 component that is going to be looking at research.  
23 The research program is being put together at -- or,  
24 the agenda, I should say, is being put together at  
25 this time, and in the President's initiative,  
26 research is part of that overall component.

1           You are going to hear from Dr. Gomez, in a  
2 little bit, about USDA's efforts and we expect all  
3 research organizations to be encouraged to look at  
4 the problems that we have.

5           I recognize that probably some of the  
6 answers we need may go beyond what is typically  
7 agricultural research. Some of it is going to have  
8 to be dealt with by such organizations as the  
9 National Institute on Allergy and Infectious Disease,  
10 for example.

11           What is the level of organism that would  
12 cause an infection? We -- an infectious dose of  
13 certain of these organisms may be very, very low,  
14 especially E. coli and 0157:H7 is expected to be  
15 exquisitely low, even a few organisms, perhaps where  
16 another organism may not be that low.

17           That type of data we are going to have to  
18 wait for, as time goes on, and keep the pathogen  
19 level as low as we can possibly can, but may indeed,  
20 as Tom has pointed out many times in his talk this  
21 morning, is the fact that we are going to minimize,  
22 not totally result in a abolition of these organisms  
23 in the environment.

24           So, I hope that answers your question. I  
25 can't say who is going to do precisely this. We hope  
26 that industry would join with us and fund appropriate

1 activities that they could accomplish better than  
2 perhaps government can, and we hope that even the  
3 agricultural community itself would look favorable on  
4 cooperating with their State, universities and  
5 institutions that are associated with research in  
6 cooperating with them as -- in a way to make their  
7 operations available for collectible data, and  
8 testing new concepts to see if indeed it might not  
9 improve agricultural practices to lower the risk of  
10 these pathogens being in the food supply.

11 The only way this is going to get done is  
12 if we all work together at it, and we're going to  
13 look very heavily toward agriculture to be the big  
14 player, the U.S. Department of Agriculture, that is,  
15 to be the big player. But I think State Universities  
16 and industrial research organizations also have to  
17 play a role.

18 MR. NELSON: Yes?

19 DR. HADDON: I'm Dr. Bill Haddon. I'm the  
20 research leader for Food, Safety and Health at the  
21 U.S. Department of Agriculture's Research Laboratory,  
22 the Western Regional Research Center that's in  
23 Albany, California.

24 I wanted to address the previous question  
25 from Donna, and to say that our laboratory has had an  
26 approximate 50-year history with working with the



1 fruit and vegetable industry in California.

2 Two years ago, in our Food, Safety and  
3 Health Program, we recognized that pathogen control  
4 in fruits and vegetables would be important, and we  
5 are in the process of integrating that very strongly  
6 into our program.

7 We're, of course, very excited as  
8 scientists about some of the research opportunities,  
9 but what we feel is a very strong need to work with  
10 the industry, particularly here in California.

11 So, again, my name is Dr. Bill Haddon,  
12 Western Regional Research Center of the Department of  
13 Agriculture in Albany, California, across from  
14 San Francisco, and we are certainly actively seeking  
15 research partnerships in this area.

16 Thank you.

17 MR. NELSON: Next question? Well, if you  
18 have no other questions right now, I'd like to bring  
19 Dr. Rick Gomez from USDA to give his presentation.

20 DR. GOMEZ: Good morning. And thank you  
21 for being here. It's great to see so many people.

22 I've been asked to explain, more or less,  
23 the role of USDA in this initiative on fresh fruits  
24 and vegetables.

25 USDA is such a big entity that it has many,  
26 many roles it can play and will play in this

1 initiative, but let me start with the title of the  
2 initiative, which says "Foreign and Domestic."

3 And we do have programs at USDA that are  
4 foreign and some that are domestic, and let me bring  
5 you some of the foreign ones. Before an agricultural  
6 service, a promoter of U.S. agriculture in other  
7 nations, they have a role to play in this initiative.

8 They, through their promotional activities,  
9 through their international cooperation and  
10 development activities, and in cooperation with the  
11 U.S. aid programs, can influence some of the  
12 agricultural practices in other areas.

13 So they have a fairly strong outreach  
14 capability, and we hope to bring that along to other  
15 lands.

16 On the domestic side, and one that plays a  
17 pivotal role in protecting American Agriculture, is  
18 the Animal and Plant Health Inspection Service, and  
19 they have point-of-entry inspection capabilities, and  
20 do, throughout the U.S. border.

21 They can also play a role in this through  
22 outreach because they touch other areas -- other  
23 countries.

24 On the domestic side and the agency I  
25 represent, by the way, the -- is the Cooperative  
26 State Research Education and Extension Service, which

1 is a union of both the land grant and agricultural  
2 experimentation system and the extension system  
3 throughout the United States.

4 We, in that capacity are the extramural arm  
5 of the USDA in outreach and research activities.

6 You've heard the gentleman from ARS,  
7 Agriculture Research Service. They are the  
8 intramural research arm of the USDA, and they also  
9 serve some of the regulatory activities of USDA.

10 I know that ARS has redirected resources to  
11 address this initiative. My agency is also  
12 redirecting some resources to address this issue.

13 There was a question of who is going to do  
14 the research?

15 Well, I think ARS is partly going to do the  
16 research on agriculture practices. Our system is  
17 going to do some of the research on agriculture  
18 practices through either redirection or through new  
19 monies being appropriated under the fiscal year '99  
20 budget.

21 We have a blanket request, which is at the  
22 Office of Management and Budget, at this time, for  
23 FY '99, and there will be similar requests for years  
24 thereafter.

25 But let me tell you the way we operate, who  
26 we are, my agency. As I said, we are the union or

1 the merging of Experiment Station and Extension  
2 Services.

3 We are the Federal partner of that system,  
4 and we fund only about 20 percent of the total monies  
5 being spent on research and extension throughout the  
6 U.S., and our budget is -- I think it's upwards of  
7 one billion dollars.

8 So you can imagine the magnitude of the ag  
9 research and extension activities.

10 The reason that we are both research and  
11 extension is not by chance.

12 It is a very logical union.

13 We are a feedback mechanism within  
14 ourselves. Extension reaches down to the local  
15 level, brings to research the needs and wants of the  
16 producers, that researchers do the research required,  
17 doing the priority set at the local regional  
18 multi-state and national levels, and extension  
19 delivers these programs to the local producer.

20 So it's a complete feedback mechanism, and  
21 that is one of the things that we need to try to  
22 accomplish in this initiative.

23 We need to get industry involved, and have  
24 it be a partner at the table, the same as FDA is, and  
25 the same as USDA is, because industry can and will,  
26 through its educational activities, help in promoting

1 the safe production of fruits and vegetables.

2 So I think that the voluntary guidelines  
3 that are going to be the product of this group,  
4 working with industry, working with FDA and USDA,  
5 working with the land grant universities, and by the  
6 way, let me see if I can remember how many of those  
7 there are.

8 There are over 100 in the U.S., including  
9 Puerto Rico and the Pacific islands. So there are  
10 quite a few land grant institutions around.

11 We are the research outreach and  
12 educational arm of the United States Department of  
13 Agriculture.

14 My agency, the Agricultural Research  
15 Service, the Economic Research Service, are in effect  
16 under one mission area in the department.

17 We are separate from the others, such as  
18 the Food and Safety and Inspection service, but we do  
19 work across mission areas, obviously. We need to  
20 work across all areas here to achieve a safer product  
21 for the U.S. consumer.

22 One of the things that we also need to  
23 include, at least in our thoughts, is that it's not  
24 only agricultural producers that need to be involved  
25 in this. It's the whole gamut. I know Tom has said  
26 it before, but we need to try to educate the whole

1 spectrum, from the foreign, to the consumer, to the  
2 person that eats the stuff.

3 So we need that. And some of our agencies  
4 such as the one I -- I'm with -- have the  
5 capabilities, but we need to bring others -- others  
6 in. We need to bring, within USDA, for example, some  
7 of the food-stamp-type activities. We need to bring  
8 those in to really make this work.

9 If you just pinpoint one area, the  
10 production area and leave the other ones untouched,  
11 it won't work. It will require all of us to be  
12 involved in this.

13 I will be around, but USDA is always around  
14 somewhere. If you have some questions, I'll be more  
15 than glad to answer them.

16 As we go to lunch, please don't forget to  
17 eat your veggies, okay? They're safe.

18 MR. GARDINE: Or fruit salad.

19 DR. GOMEZ: Or fruit salad.

20 MR. NELSON: Do you have any questions for  
21 Dr. Gomez right now? What a quiet audience here.  
22 Two things before I let you go to lunch. All the  
23 presenters, please be seated up here so we can get  
24 started when you come back from lunch.

25 Please be back here at quarter to 1:00.  
26 You will be free for one hour. Okay?

1                   (A luncheon recess was taken between 11:45  
2                   and 12:56 p.m.)

3                   MR. NELSON: All right. Let's get started.  
4                   Would everyone come in, please, and be seated?

5                   Each person will introduce himself and  
6                   continue on. Tom Gardine will also sit up here to  
7                   answer any questions you may have. Dave?

8                   MR. RIGGS: Okay. My name is David Riggs.  
9                   I am President of the California Strawberry  
10                  Commission. I appreciate the opportunity to comment  
11                  today on the proposal to develop good agricultural  
12                  practice guidelines.

13                  I have been asked to kick off the  
14                  discussion on behalf of industry, and I want to begin  
15                  by saying that our comments today should not be in  
16                  any way construed to mean that we are opposed to any  
17                  efforts to enhance the quality of food safety in  
18                  American Agriculture. I think many of us are very  
19                  active in developing programs specific to our  
20                  industries, in trying to develop guidelines that are  
21                  useful and applicable in the field.

22                  In fact, as I listen to Dr. Gardine's  
23                  presentation, I said I've heard that speech before.  
24                  In fact I've given that speech before. Ray Nelson  
25                  has heard me give that speech before.

26                  Well, I think, as you also correctly

1 pointed out, the devil is in the details, and there  
2 are some areas where we do have some concerns, and we  
3 appreciate the opportunity to express some of our  
4 concerns in this meeting.

5 The California strawberry industry is very  
6 acutely aware of the food safety issue. Our industry  
7 has suffered through two food safety scares in the  
8 last two years, neither of which was of our making.  
9 It has been referred to already in this meeting.

10 In 1996, Cyclospora outbreaks in several  
11 cities in the U.S. and Canada were initially  
12 attributed to California strawberries, and ultimately  
13 it was determined that the most likely source of the  
14 illnesses was raspberries from Guatemala, but before  
15 consumers got the correct information, they quite  
16 understandably avoided the purchasing of  
17 strawberries, and the effect upon our farmers was  
18 devastating.

19 In a four-week period our industry lost  
20 between 20 and 40 million dollars. We estimate for  
21 the Counties of Santa Cruz and Monterey County, the  
22 loss was about \$2,000 per acre. Many farmers did not  
23 survive.

24 Our acreage declined 15 percent in the  
25 northern districts in 1996 to 1997, which equates to  
26 a loss of 5,000 agricultural jobs, and that's a very



1 substantial economic impact on agricultural  
2 communities like Santa Maria and Watsonville.

3 I think that's particularly important  
4 because, in our view, the real cause of these losses  
5 was not Cyclospora. It was haste, carelessness,  
6 inaccuracy and a lack of adequate science.

7 Some public health officials rushed to  
8 conclusions, and media reports inflamed the situation  
9 and there was clearly a dearth of scientific  
10 information about the Cyclospora organism.

11 I want to add that the Cyclospora case  
12 shows that the public is ill-served by inaccuracy.  
13 When the Houston Health Department told people not to  
14 consume California strawberries, many restaurants  
15 immediately substituted Guatemala raspberries.

16 Again, in April of this year, children in  
17 Calhoun County, Michigan, became ill apparently from  
18 the consuming of frozen strawberries that were grown  
19 in Mexico last year and processed by a plant in  
20 California.

21 The Hepatitis A infections were clearly not  
22 related to fresh strawberries, nor were they ever  
23 associated with strawberries grown in California.  
24 But again, the careless use of words, such as  
25 headlines reading, "Tainted berries," confuse and  
26 alarmed consumers, and again it was the California

1 farmer who suffered.

2 And, again, losses in the tens of millions  
3 of dollars affected farmers and farm workers in  
4 communities where strawberries are grown.

5 Now, in many ways, in both of these  
6 situations, it was FDA, CDC and our State health  
7 agencies that added rationality to these situations  
8 by taking the time to seek out more facts by  
9 demanding more information, and by doing all they  
10 could to ensure clear communication reached the  
11 media.

12 So the agency's responsibilities and  
13 credibility in this area is clear, and it's very  
14 important to public health.

15 But frankly, we are concerned that the  
16 haste with which these guidelines are being  
17 developed, with which FDA appears to be moving and  
18 developing these guidelines, may put the agency in  
19 danger of falling into some of the same traps that  
20 afflicted the Cyclospora and Hepatitis incidents.

21 Therefore, we urge you, as you prepare  
22 these guidelines, to take the time necessary to  
23 develop the guidelines properly, be careful whether  
24 you are in communication, and ensure that there is  
25 an adequate scientific foundation for the  
26 recommendations that you make.

1           Most importantly, you should be cognizant  
2 of the substantial infrastructure of State and  
3 Federal regulation in place to protect the consumer,  
4 and many industries, including the strawberry  
5 industry, have taken progressive steps to further  
6 ensure the safety of our products.

7           Now, we appreciate the acknowledgment that  
8 we've heard so far today, that there is a substantial  
9 structure of regulation and law which is already in  
10 place in this area, but I have to say that, in some  
11 of the previous rhetoric we've heard, we've been  
12 concerned that this acknowledgment has been lacking.

13           While neither the Cyclospora nor the  
14 Hepatitis incidents were related to strawberry  
15 production, we clearly learned firsthand how  
16 intensely the consumer feels about food safety  
17 issues, and we tried to respond proactively.

18           In the midst of the Cyclospora incident, we  
19 established a Cyclospora research panel, and the  
20 strawberry industry funded about six of the leading  
21 industries in the United States and Canada to do  
22 substantial research on improved detection, improved  
23 treatment and improved basic understanding of the  
24 knowledge of Cyclospora.

25           Again, Cyclospora was not our problem, but  
26 we felt this was research that needed to be done and

1 we came to the plate with the money and with research  
2 grants to make sure that research was conducted.

3 Secondly, we proactively began work in  
4 mid-1996 on developing a Quality Assurance Program to  
5 add that extra measure of safety to demonstrate our  
6 commitment to producing a safe product for the  
7 consumer.

8 We worked proactively with the California  
9 Departments of Health Services, with Food and  
10 Agriculture, with FDA and the University of  
11 California to develop a comprehensive Quality  
12 Assurance Program.

13 I think there are two points that I would  
14 like you to note from our experience in developing  
15 this program.

16 First, it's taken us about 18 months of  
17 concentrated work, on a crop that we know very well,  
18 to learn all we needed to learn to ensure that our  
19 program meets or exceeds all legal and regulatory  
20 requirements, is doable in the field, and is based on  
21 solid science.

22 We are concerned that FDA is trying to do  
23 the same job for all commodities throughout the  
24 United States in about a third of the time without  
25 the in-depth knowledge of production and legal issues  
26 that we began with.

1           Second, as which noted before, there is a  
2   substantial framework of State and Federal  
3   regulation, as well as industry standards, in place  
4   to ensure that agriculture provides a safe product  
5   for the consumer.

6           And to illustrate that, most of our Quality  
7   Assurance Program is a matter of ensuring and  
8   documenting all the steps the farmer takes to be in  
9   compliance with California's stringent regulations on  
10  worker safety, field sanitation and pesticide usage.

11          Because this framework exists, we think the  
12  haste with which FDA is approaching this task is  
13  unwarranted. There is time to make sure that it's  
14  done properly, and as we said before, inaccurate  
15  information or bad decisions can create a public  
16  health risk.

17          I say -- we would say the first step that  
18  we would recommend is to take the time necessary to  
19  understand current farming practices, to spend more  
20  time in the field, get to know what's already being  
21  done, and establish the scientific foundation for  
22  these regulations.

23          In summary, I would like to leave you with  
24  four main points:

25          First of all, we would urge you to take the  
26  time and make the effort to understand farming

1 systems as you write these guidelines.

2 You, and those who are drafting this  
3 document, need to get into the fields during the  
4 harvest season, during the production process to  
5 understand farming systems.

6 Number 2, acknowledge and understand  
7 existing State and Federal laws and regulations  
8 relevant to food safety and agricultural practices,  
9 learn more about what specific industries are already  
10 doing and have already learned in the process.

11 Number 3, and this is perhaps my most  
12 important point, as you move forward with this, you  
13 must do so on a generic basis.

14 We are very adamant in our feeling that  
15 there is little to gain and a great deal of risk to  
16 the economic well-being of farmers, communities and  
17 farm workers if you identify specific commodities for  
18 special attention.

19 However you devise your criteria, there  
20 will be a potentially ominous spectre hanging over  
21 any crop that you identify for special treatment.

22 And, finally, you need to ensure that  
23 whatever recommendations are part of these guidelines  
24 are based on sound science and can be realistically  
25 and legally implemented in American farming.

26 Again, the California strawberry industry

1 has paid a dear price for the education that we've  
2 received on food safety, microbial contamination and  
3 the intensity of the consumers' concern about food  
4 safety.

5 We've learned a lot in the process of  
6 developing our Quality Assurance Program. We've  
7 worked closely with both our State and Federal  
8 agencies in developing that program, and we've  
9 encouraged our national and State associations to be  
10 a source of information for FDA in this process.

11 I would like to conclude by saying, on  
12 behalf of the strawberry industry, that we'd be happy  
13 to share what we have learned, facilitate field tours  
14 or provide additional insights that might be valuable  
15 in this process.

16 Thank you.

17 MR. GARDINE: Thank you.

18 MR. NELSON: I'd like to introduce Matt  
19 McInerney, Senior Vice President of the Western  
20 Growers Association, which also represents farmers in  
21 California and Arizona.

22 MR. McINERNEY: Thank you, Dave, and thank  
23 you for the opportunity to present comments on behalf  
24 of the Western Growers Association on the proposed  
25 agricultural practices.

26 As I look out in the audience, many are

1 members of the Western Growers, but perhaps for those  
2 who are not familiar with us, the Western Growers  
3 Association is a trade association representing  
4 growers, packers, shippers and processors of fresh  
5 produce in California and Arizona.

6 We represent about 90 percent of the fresh  
7 produce grown, and it equates to over half of the  
8 fresh produce consumed domestically.

9 Western Growers and its members are  
10 extremely proud that our industry contributes to the  
11 health of the American consumers by providing to them  
12 nutritious and safe produce.

13 It is a well-documented fact that the  
14 benefits of eating fresh fruits and vegetables far  
15 outweigh any risk of becoming ill due to a Cyclospora  
16 out-break.

17 In fact, it has been suggested you may  
18 suffer greater threats or risks by not regularly  
19 consuming a minimum of five servings of fresh fruits  
20 and vegetables daily.

21 Based on reports gleaned from government  
22 statistics, they tell us that about three percent of  
23 all fresh produce, food-borne outbreaks can be traced  
24 back to originating in the field, packing house,  
25 processing and post-harvest activities.

26 In our personal experiences and in



1 following the current management theories, regulators  
2 should focus most of their remedial measures on those  
3 post-harvesting processing activities that seem to  
4 cause the largest reported problems.

5 Therefore, before FDA proceeds too quickly  
6 to concentrate its efforts exclusively on the fresh  
7 produce industry, FDA should keep in mind this low  
8 statistical number of three percent when it moves  
9 forward.

10 As many of you might know, Western Growers  
11 has been aggressively engaged in the food safety  
12 issue for the past year and a half.

13 We are very proud of the efforts we have  
14 accomplished today, and will continue in the future  
15 on the food safety issue.

16 In fact the partnership with the  
17 International Fresh Fruit and Cut Produce  
18 Association, along with the California and Arizona  
19 Fresh Produce Industry has developed, as I think Ray  
20 Nelson showed, the Voluntary Food Safety Guidelines  
21 for the fresh produce industry.

22 In partnership with the produce industry  
23 and government regulators, which is a key component  
24 to the production of our document over the past year,  
25 we've learned a lot about food safety, how to write  
26 guidelines and how to communicate food safety

1 principles to our growers, shipper and processor  
2 members.

3 Our comments today reflect those  
4 experiences that we have gained through that process.

5 First, we strongly encourage the President  
6 and the Food and Drug Administration to slow the  
7 process down.

8 We frankly are concerned and don't  
9 understand the need to move so quickly with these FDA  
10 good agricultural practices.

11 For example, our process took us, in the  
12 final drafting stages of the document, eight months  
13 to develop the draft guidelines, and that was with  
14 considerable input from the industry, growers,  
15 shippers, packers, processors and most importantly,  
16 from government regulators.

17 We are concerned that, in FDA's  
18 inexplicable haste, the FDA could develop GAPS that  
19 could be one, unnecessary, and potentially redundant  
20 to current State and Federal law.

21 Perhaps our experiences might have been  
22 unique. The guidelines that were developed with IFPA  
23 and WGA were written by those growers, packers  
24 shippers and processors who live with them day-in and  
25 day-out, and who deal with food safety on a daily  
26 basis. They have field, cooling, packing, processing

1 and transportation experience.

2 Further, we have the input in our document  
3 from a panel of scientists familiar with food safety  
4 issues.

5 Finally, the constant interaction with  
6 regulatory bodies provided a great deal of validation  
7 for the final document of our Food Safety Guidelines.

8 It is with the greatest of respect to the  
9 panel and to FDA that FDA has not had the same  
10 on-ground interaction which WGA believes is critical  
11 in developing meaningful GAPs.

12 For this reason, we respectfully suggest  
13 that the President, and through him, the FDA, slow  
14 the process down until FDA has had an opportunity to  
15 visit and interact in fields, packing houses and  
16 processing plants, and to work with local growers,  
17 packers and shippers, as well as processors, and our  
18 State agricultural health officials to develop GAPs.

19 Secondly, we strongly encourage FDA not to  
20 develop crop-specific GAPs. If the FDA identifies  
21 specific commodities for which specific GAPs need to  
22 be developed, government will potentially taint these  
23 commodities in the eyes of consumers.

24 In other words, you will totally undermine  
25 the confidence of consumers in specific commodities,  
26 with no scientific basis, which can only serve to

1 cause additional significant economic damage to  
2 particular commodities.

3 Again, keep in mind that the three percent  
4 statistic is an extremely important issue to keep in  
5 mind as the GAPs move forward.

6 Again, we are extremely proud that the  
7 fresh produce industry is continuing to minimize  
8 microbial contamination.

9 In California and Arizona, we are actively  
10 engaged in addressing food safety issues, and have  
11 been for some time. Before focusing all or part of  
12 its effort on field to --- before focusing all or a  
13 large part of its efforts on field to packing to  
14 processing operations, which are a minor contributor  
15 to food safety problems, we must have equity, parody  
16 and good management practices by FDA first.

17 By focusing primarily on produce  
18 agriculture, the segment of the fresh produce  
19 industry, FDA is in effect singling out, or in effect  
20 punishing that segment of the industry which is doing  
21 the most to move forward the food safety issue and  
22 reduce microbial contamination.

23 Therefore, again, we emphasize the process  
24 should be slowed down and the focus on the production  
25 side of the fresh produce industry should be  
26 re-examined.

1 I'd like to emphasize that we are not  
2 opposed to guidelines. As I indicated, we developed  
3 our guidelines and currently have an outreach  
4 education program that is actively involved with our  
5 members.

6 We developed our own guidelines. However,  
7 we developed them locally. They were written by  
8 industry growers, packers, shippers and processors,  
9 who are very capable and were assisted by scientific  
10 expertise in government cooperation and partnership.

11 We believe that our approach, a deliberate  
12 and pragmatic process, with a strong educational  
13 component, has resulted in a comprehensive, but  
14 ever-evolving document that will change as time and  
15 science and techniques evolve.

16 We suggest that the potential of the  
17 WGA-IFPA Voluntary Food Safety Guidelines be used as  
18 a model that FDA could consider.

19 Again, please slow down your effort, do not  
20 develop specific crop GAPs, and recognize that the  
21 fresh produce industry has been, is, and will  
22 continue to be, actively engaged in the food safety  
23 matters.

24 Those are my brief comments today, and I  
25 appreciate the opportunity.

26 I would like now to provide an introduction

1 to Leslie Caviglia, Vice President Member Services  
2 with the California Citrus Mutual.

3 MS. CAVIGLIA: Thank you, Matt. And I want  
4 to express the same sentiments that we welcome the  
5 opportunity to provide comments today.

6 I am here representing California Citrus  
7 Mutual, which is a trade association for the citrus  
8 industry. We represent growers throughout the State.

9 And I'm also here speaking as a farmer. My  
10 husband and I are citrus growers in the San Joaquin  
11 Valley, and kind of the typical small farmer that you  
12 would think of.

13 And I'm here as a very proud, but have  
14 frustrated, farmer with this process.

15 We in citrus are very proud of the product  
16 that we produce. It's very healthy, it's very  
17 wholesome. It's a unique product. It's got a thick  
18 skin around it.

19 We already use low volume irrigation. We  
20 harvest with growers already. We don't utilize fruit  
21 that's dropped on the ground. Those are already  
22 established practices that we have.

23 As a result, we already have an excellent  
24 food safety history in our industry. We know of no  
25 problems that have ever resulted from microbial  
26 contamination. We're very proud of that.

1           Nonetheless, we still, as an industry, took  
2 the initiative. California Citrus Mutual, working in  
3 conjunction with the California Citrus Quality  
4 Council, which is -- works in conjunction with our  
5 research board to develop our own good ag practices.

6           We work with researchers and scientists  
7 that are familiar with our industry. We worked with  
8 industry experts to develop our own document. We  
9 utilized that excellent knowledge and excellent  
10 history that we already have in producing a safe  
11 product, and we are taking the responsibility for  
12 continuing the outreach and the education to reach  
13 our growers and our packers and shippers with that  
14 information.

15           We also know that we are going to  
16 continually review and to adapt that document to meet  
17 the changes that are continually going on in our  
18 industry, and we think that we are best situated to  
19 do that, again because of the excellent history that  
20 we have.

21           So I come frustrated now to hear that  
22 government thinks they need to come tell us how to do  
23 something that we already believe, and have a history  
24 of knowing, that we do well.

25           I do believe that the document that has  
26 been prepared is too much of a cookie-cutter document

1 that does not take into account the differences in  
2 growing regions and the variations between States and  
3 the government regulations that are already in place.

4 I also believe that some of the  
5 recommendations are impractical. An example that I  
6 would use, a specific one, would be that it takes my  
7 husband and I about three-acre feet of water to grow  
8 an acre of citrus each year.

9 On good years like this one, a third of  
10 that is going to come from rainfall. Another third  
11 is going to come from the ground water, and a third  
12 will come from the Federal Water Project.

13 To hear now that we should be testing our  
14 wells to test the quality of that water, and yet we  
15 have nothing to reflect back on what would be a  
16 satisfactory quality level for the water, is  
17 frustrating.

18 It's testing, and for what purposes?

19 Secondly, with regards to the Federal Water  
20 Project, water that travels for literally hundreds of  
21 miles through the open canals, and so on, all of a  
22 sudden now we are responsible for the quality of that  
23 water.

24 I have visions now of the Feds putting up  
25 fences along the entire canal to keep out the humans  
26 and the rodents and other wildlife that are not



1       supposed to become involved with the water.

2               It just seems impractical, and, again, does  
3       not reflect the local conditions.

4               One part of our frustration also comes from  
5       the implication that we wouldn't do this just because  
6       it's the right thing to do, but, even more  
7       importantly, it's a market-driven situation for us.

8               We've got to produce a safe product. We've  
9       certainly seen, time and time again, that, when there  
10      is a problem, whether it be real or imagined, the  
11      entire produce industry receives a black eye.

12              The specific commodity that it involved,  
13      then, has great economic damage done to it. It's in  
14      our best interests to be doing this, and doing it  
15      correctly, and that's what is driving us.

16              We, too, as Matt indicated, are frustrated  
17      that the emphasis seems to be on the growing end  
18      where the risk seems to be the lowest, that three  
19      percent of the food-borne illnesses, and that more of  
20      the emphasis is not being put -- or isn't even  
21      beginning with the retail food service and home  
22      practices that are really critical to the food safety  
23      issues.

24              Our final frustration, at least on my list,  
25      comes from the fact that this is being touted as  
26      guidance, and we have, time and time again, as

1 farmers in California, seen guidance and voluntary  
2 things turn around and very quickly become  
3 regulations.

4 We are skeptical, and that is the kind  
5 word, I think, on behalf of our growers, to say that  
6 these will not in a very short time become  
7 regulations that will be costly and not necessary --  
8 most importantly, not necessary.

9 We have some questions about whether the  
10 full ramifications of these guidelines have been  
11 studied, and if in fact they will, because we think  
12 it is important that it be considered.

13 How will guidelines such as these, that  
14 could easily become regulations, affect the market  
15 supply of the healthy produce that we know needs to  
16 be provided throughout our country, and at an  
17 economical level so that it can be afforded by all  
18 segments of our consumer base?

19 What economics effects could these actions  
20 have on the viability of growers throughout the  
21 country?

22 Is it going to become so cost-prohibitive  
23 that in fact many of our smaller growers are run out  
24 of business?

25 How will it affect overseas trading.

26 Day-in and day-out, the President of

1 California Citrus Quality Council is here, we deal  
2 with trade barriers in other countries. Whether this  
3 be perceived as a false trade barrier, or an excuse  
4 for other countries to keep us out of their trading  
5 areas, are real issues that we think need to be  
6 studied before this goes further.

7 We believe that this process is flawed,  
8 most importantly because it is moving so quickly.

9 We, too, took months to develop our own  
10 document, using our industry experts, using the  
11 people who are very familiar with our product, and it  
12 took us several months to do, and still this one is  
13 being turned over in just a very -- seemingly short  
14 period of time.

15 We also question whether the research and  
16 practical experience is in place to be developing  
17 these types of documents.

18 Yesterday our -- the President of our  
19 organization was in Washington, D.C., and he was told  
20 by one of our Congressmen that our Congressman had  
21 been assured that representatives from FDA would be  
22 in the San Joaquin Valley in January to conduct field  
23 tours, and I think that is laudable, and we look  
24 forward, and hopefully, today, we can perhaps receive  
25 a date that you will be coming to the San Joaquin  
26 Valley.

1           From a very selfish perspective, that's  
2 great, but I think there must be much more  
3 exploration and research done before this goes  
4 forward.

5           Please don't get me wrong. California  
6 Citrus Mutual does support the concept of food  
7 safety, and we believe that our practices that we  
8 already have in place and the steps that we've taken,  
9 speak for themselves.

10           Good ag practices, good manufacturing  
11 practices are important, and again our actions speak  
12 louder than any words, but as you go ahead and go  
13 forward to make your 90-day report to the President,  
14 we are adamant that you request that this process be  
15 slowed down so that it can be -- not just done, but  
16 done correctly, that it not be commodity-specific.  
17 That is just not necessary. That it be based only on  
18 sound and proven research, which is based on good  
19 field research and not test-tube research.

20           And that it be taken only after much more  
21 study and an understanding of the entire industry is  
22 undertaken by the decision-makers that are involved  
23 in this process.

24           Again, we support good food safety and good  
25 practices, but we believe that is best left in the  
26 hands of those who are practicing it.

1 I'd like to now introduce Dick Nutter, who  
2 is the Ag Commissioner of what is known as the "salad  
3 bowl of the world," Monterey County.

4 MR. NUTTER: Thank you, Leslie. That was  
5 my line.

6 I'd like to welcome you here to Monterey  
7 County, and on behalf of County Agricultural  
8 Commissioners throughout the State.

9 California is unique, and it was brought up  
10 during the testimony here earlier, that you need to  
11 look at reasonable commodity diversity in coming up  
12 with your decisions.

13 California is unique, not only because of  
14 our climatical conditions and our ability to grow a  
15 lot of crops, we're unique in the fact that we have  
16 this system called the "County Agricultural  
17 Commissioner System."

18 There is a County Ag Commissioner in each  
19 County, each of the 58 counties in California, and we  
20 are appointed by the Board of Supervisors after  
21 recommendations by the Director of Pesticide  
22 Regulations and the Secretary of Agriculture, at the  
23 State level.

24 So we work administratively under those  
25 State officials, so we've heard a lot this morning  
26 about the Federal and the State officials that are

1 available, but I'm here to tell you that, in  
2 California, we have some other local officials that  
3 are able and willing to a part in this whole  
4 process.

5 We are involved with every grower in the  
6 County. We're on every piece of property in the  
7 County. We know the -- the crops, the diversity, the  
8 cultural practices. We are a major resource, when it  
9 comes to dealing with County issues.

10 Just involved with -- as a result of the  
11 Cyclospora issue and E. coli issues, the guidelines,  
12 the volunteer guidelines that were developed by  
13 California agricultural industry, members here  
14 recently started right here in this County, where it  
15 was a partnership between some State officials and  
16 members of my staff, to organize the first meetings,  
17 along with Ray Nelson, and others in the FDA, to say,  
18 "We've got a problem here. What are we going to do  
19 about it?"

20 So I think that the resource that we have  
21 here in Monterey County is the Agricultural  
22 Commissioner's ability to work with University  
23 Extension people, with the Federal and State  
24 organizations, make this an opportunity to take the  
25 message that we're going to try to get out and get it  
26 to all people.

1           Looking at agriculture here in Monterey  
2 County, we're a two-billion-dollar gross-value  
3 industry.

4           In fact, we rank Number 4 in total value in  
5 the nation, and the leading vegetable crop-producing  
6 County in the nation.

7           What we've seen over the last -- the last  
8 few years, you know, if you want to take it in time  
9 frames of decades, where, how did we get to the  
10 position where we are right now?

11           Looking back 20 years ago, we produced  
12 about 55- or 60,000 in acres of head lettuce, and  
13 today we're producing about 70 to 75.

14           We were producing 3,000 acres of leaf  
15 lettuce, and last year there were 35,000 acres of  
16 leaf lettuce. Broccoli has gone from about 20- to  
17 25,000 acres to 55- to 60,000 acres.

18           This has all been driven by consumer demand  
19 and, obviously, there has been an effort by the  
20 industry to support the 5-a-day program and others,  
21 but I think that consumers, in general, are more  
22 health-conscious than they have been in the past, and  
23 they are really demanding this at this time.

24           Part of that leaf lettuce has gone to 18 to  
25 20 romaine alone. You can see it in supermarkets  
26 where they have made shelf space just for salad

1 products. So it's been a major change, and it hasn't  
2 come about overnight, although it seems like those  
3 packaged products just appeared there.

4 But it's been over these many years where  
5 it's been trial and error with people dealing from  
6 all the processes: Food safety issues, from  
7 packaging, transportation, from marketing.

8 All those sorts of things are in place to  
9 develop this new technology and be able to provide  
10 these products to our consumers, not only here, but  
11 throughout the United States.

12 We look at regional and commodity  
13 differences. I think this is really important  
14 because I've seen, over the years, when --  
15 particularly with EPA making decisions on pesticides,  
16 where they will sit around a table back in Washington  
17 and say, "Oh, what's an artichoke? I wonder, how  
18 does that grow?"

19 Maybe we can -- you know, push this type of  
20 approach. When they don't understand what the  
21 commodity is, how it grows, or much about it, so I  
22 think that it is important following up on the FDA's  
23 tour in California. I think that is really  
24 significant that we look at regional and commodity  
25 differences.

26 The other issues about compost and manure,



1 when you look at about 60 days and 120 days, some of  
2 our crops from seed to harvest are 45, 50, 60, 70  
3 days.

4 So we really need to take those types of  
5 things into consideration before you would make a  
6 flat prohibition against a specific time frame. It  
7 would have to be some qualifications that would come  
8 into place there.

9 I think, in general, we have been able to  
10 form some good working partnerships with our  
11 industry, and with our State and Federal partners  
12 that have been beneficial for the industry, and so I  
13 would just like to again reiterate that we have a  
14 mechanism here to provide information to the  
15 agricultural community on an individual basis, and so  
16 I'm offering that as part of our efforts in  
17 cooperation.

18 And I think that this County agricultural  
19 system allows us to deal with State and other issues  
20 and mold them to the County -- the County  
21 differences.

22 You don't want to implement the same type  
23 of conditions on -- that you have for cotton into a  
24 lettuce crop, or some other type of annual crop or  
25 short-growing season crop.

26 So I think that the next speaker, Dave

1 Bolster, from El Dorado County, epitomizes, you know,  
2 what can happen when a County Agricultural  
3 Commissioner perceives that there is a need in the  
4 community, and sets out to address that issue.

5 So, Dave?

6 MR. BOLSTER: Thank you, Dick, and I would  
7 like to provide Bill Snodgrass with some kudos for  
8 his involvement. Bill Snodgrass is the El Dorado  
9 County Agricultural Commissioner.

10 Bill Snodgrass, back in March of this year,  
11 when Stu Richardson and DHS convened a State-wide  
12 meeting of the apple growers in California, Bill  
13 Snodgrass took a leadership role and he took a  
14 leadership role in our industry, which, at times, is  
15 unconventional for Agricultural Commissioners, in  
16 terms of the degree of risk, that Bill took in terms  
17 of putting himself out on the line with his  
18 industry.

19 So I think Bill deserves a great deal of  
20 credit as our Agricultural Commissioner. A little  
21 bit of background on the Apple Hill Growers.

22 The Apple Hill Growers are a collection of  
23 approximately 50 fruit growers, wineries, Christmas  
24 tree growers in El Dorado County.

25 We are a small -- we are a group of growers  
26 in a small area, probably 15 to 20 square miles, and

1 we, in terms of the development of a Quality  
2 Assurance Program, are very fortunate in that we had  
3 a relatively small group of seven processors that  
4 have known each other for a long time, and so we were  
5 in a favorable condition, in a position to be able to  
6 put together a Quality Assurance Program.

7 The Apple Hill GAP is a collaborative  
8 effort between industry, government and the  
9 scientific community.

10 FDA, DHS, University of California and, of  
11 course, our industry, worked together to create the  
12 Apple Hill Quality Assurance Program. The Apple Hill  
13 QAP is a comprehensive, integrated program for  
14 voluntary guidelines for apple production and cider  
15 processing that enhance the safety and quality of  
16 unpasteurized apple juice.

17 When we say that, we're talking about  
18 addressing those critical points from bloom to  
19 bottle, from that first cultural practice in the  
20 field in the winter time, and in the springtime,  
21 through the final distribution of the product to the  
22 customer, to the consumer.

23 So, what we have done is address, from the  
24 basis of science, address all those steps in that  
25 process, to ensure that we have reduced the risk of  
26 microbial contamination of that product.

1 I would like to thank some people in the  
2 room today, Dr. Linda Harris at UC Davis, Cooperative  
3 Extension Service, providing a great deal of  
4 scientific background for our program, Stu Richardson  
5 and Jim Waddell from DHA.

6 So I have to tell you that, when the  
7 industry gathered in Sacramento back in March,  
8 when Stu got up to speak and it became evident  
9 that the approach from DHS was that of a -- an  
10 industry-government partnership to solve a problem,  
11 I have to tell you that, generally speaking, the  
12 industry was fairly shocked at this approach,  
13 because that has not been the model traditionally,  
14 historically, and I think the Apple Hill QAP is a  
15 demonstration of what this model and this approach  
16 can achieve.

17 You know, I think the critical aspect of  
18 this notion of government-industry partnership is,  
19 that it is so-called -- it's a so-called bottom-up  
20 approach, where it is based from the industry, from  
21 the people out on the field practicing their trade,  
22 and, of course, maybe some of the people in the  
23 industry would call that a top-down approach, with  
24 the government on the other side, but there is a  
25 sense of ownership amongst the people who have to  
26 execute these programs, these Quality Assurance

1 Programs.

2 They are the people in the trenches out in  
3 the field, doing the work, executing the program, and  
4 so, without that sense of ownership, I don't think  
5 you would have the same effect that you have seen  
6 with our Apple Hill program, the Quality Assurance  
7 Program, as if it were a simple regulation.

8 With the top-down approach, where from  
9 Washington, we have to pay attention to regulatorer  
10 edict, there is no sense of ownership amongst the  
11 people who will conduct that program.

12 So I really think that the notion of a  
13 sense of ownership is really critical.

14 In terms of the development of the QAP and  
15 the time frame, Stu convened the meeting back in  
16 March. At that time Bill Snodgrass and the industry  
17 up there proposed a tree-pick program, and from that  
18 humble beginning, our group of processors began the  
19 process of putting together, with the DHS and FDA, a  
20 Quality Assurance Program that is up and running, and  
21 has been fully implemented this last season.

22 And that perhaps is a distinction from some  
23 other QA programs across the country. We already  
24 have basically another year or another season under  
25 our belt. We have a program that has been fully  
26 implemented that has a compliance and verification

1 element in it. We've already exposed ourselves to  
2 our own compliance and verification element by  
3 third-party inspectors.

4 So we've had an opportunity to witness the  
5 full process from start to finish, from the  
6 development of a QAP to implementation, and to the  
7 final aspect of compliance and verification with that  
8 program.

9 So I think we have some decent experiences  
10 in a very practical and real-world sense that we can  
11 offer FDA.

12 Basically, there are six elements to our  
13 program, which are guidelines, of course. The  
14 administrative guidelines, production guidelines, and  
15 I would like to reiterate, one of the themes that  
16 we've heard so far, in terms of how we address the  
17 commodities, whether it be from the standpoint of  
18 looking at it from across the country or by region,  
19 one of our observations in developing our QAP was  
20 that this QAP was specific to our area, and we  
21 recognize that there are different practices and  
22 there are different conditions which affect  
23 commodities within -- within that commodity.

24 For example, on the West Coast, we grow  
25 very few MacIntosh. On the East Coast, that's a  
26 primary variety, so it's very easy for us to say on

1 the West coast that we are not going to use grounders  
2 or drops in our fresh juice, and we recognize that,  
3 back east, that potentially may be a problem, and  
4 those people may have a greater challenge in that  
5 issue. So there are, within commodities, a great  
6 variety, in terms of how they are produced and how  
7 they are harvested.

8 The training guidelines, I think are a  
9 really critical element of our program. Linda Harris  
10 developed these guidelines, along with Mario  
11 Moratorio.

12 They delivered the training programs and  
13 educational programs to our field workers, to our  
14 processing plant employees, to the management of our  
15 plants, and we are very grateful for their  
16 participation and their work in our QAP.

17 One comment, relative to the objective of  
18 the President's initiative, and that is that it seems  
19 to be that the objective here is grower awareness and  
20 grower training and grower education to prevent  
21 microbial contamination of the product.

22 I think you know we really need to hang our  
23 hats on that aspect of grower education, grower  
24 training, as opposed to the potential for development  
25 of regulation.

26 I would like to reiterate some of the

1 comments that we've heard, in terms of the model of  
2 government-industry partnership. It works. It has  
3 worked for us and I think it can work across the  
4 United States, in terms of producing a commodity  
5 safely, and I think that we have a concern relative  
6 to the approach that's been taken, not only the time  
7 frame but, you know, we have a model here in  
8 California that has worked, and our concern is that,  
9 for some reason, we have deviated from that model.

10 Although, you know, we credit FDA for  
11 utilizing much of the information that was developed  
12 here in California, our concern is that we have gone  
13 back to the -- you know, the old model of the  
14 top-down approach.

15 So we would like to strongly recommend that  
16 we slow down the process and go back to the  
17 fundamental notion of asking the people who are going  
18 to do the work in the field and manage the process,  
19 and deal with them first, and then develop the  
20 program.

21 We think that's absolutely critical.

22 The time frame, we had seven processors  
23 that we worked with, a very intensive effort from  
24 March until the middle of August this year, and so we  
25 have a very small group of people that worked very  
26 hard, for a short period of time, and were able to



1 pull this off, but you know, I think you have to keep  
2 that in perspective.

3 When you're looking at, in implementing the  
4 GAPs across the United States, is that the time frame  
5 is excessively -- I think ambushes it, and it's  
6 overly-optimistic to think that you could actually  
7 implement and successfully develop GAPs that are  
8 bottom up, that are -- that have buy-in from industry  
9 in that time frame.

10 With that, I will introduce Dr. Nagle from  
11 Dole Foods. Nancy Nagle.

12 DR. NAGLE: Thank you. I'm here just  
13 representing the Dole Food Company, and I just kind  
14 of want to talk a little bit about some of our  
15 company's feelings about this process.

16 Obviously, we at Dole are big supporters of  
17 food safety, and we also, however, believe that the  
18 vast majority of fruits and vegetables consumed in  
19 this country are perfectly safe.

20 We can't forget the 5-a-day message. We've  
21 spent a lot of money as a company and industry in  
22 encouraging the increase in consumption of fruits and  
23 vegetables, and the good news is this message has  
24 been successful. We have now increased average adult  
25 consumption of fruits and vegetables up to four  
26 servings a day, up from two and a half when the

1 program started.

2 So we should all applaud ourselves for that  
3 factor, and are pleased at the progress we are making  
4 on the nutritional front, actually following models  
5 set forth as good manufacturing practices, and also  
6 we recommend the use of the background documentation  
7 that was developed by Western Growers and IFPA, as  
8 well as the United Fresh Fruit and Vegetable  
9 Association.

10 There is a concern. We want to make sure  
11 that any specific recommendations are based upon  
12 sound science and respond to actual risk.

13 When we looked at the Western Growers, and  
14 IFPA documents, and the guidelines that we worked on,  
15 we felt that it was really important to have the  
16 involvement of all industry segments in this  
17 development, and that includes the growers, the  
18 packers, the shippers, because without their  
19 involvement, you really don't get an understanding of  
20 the risk.

21 We agree with the assessments of, probably,  
22 where the risk has been identified, areas of water  
23 and fertilizer, manure management.

24 We are in agreement that those areas are  
25 important, but again, we all want to make sure that  
26 they we are addressing an actual risk, and a risk

1       that can be mitigated and something can be done.

2               We heard from our friends in the citrus  
3       area, you know, you look at the water projects.

4               You look at water, you can't make an  
5       individual grower responsible for the water supply  
6       that's delivered to them by the government.

7               We feel that common sense has to be applied  
8       to risk assessment in each of these areas.

9               One of the other areas that we think is  
10      really important is that any GPs or GAPS that are  
11      implemented have to really have three things.

12              They have to be simple. They have to be  
13      understandable and they have to be measurable.

14              If you can't do those things, then how can  
15      we expect someone to follow them?

16              There are a lot of ways that we can segment  
17      the industry, and we need to be clear as to what  
18      we're looking for when we're looking at risk  
19      assessment.

20              We've heard about, you know,  
21      commodity-specific regulation. We need to be sure  
22      that, when we're identifying a commodity, that it is  
23      a commodity that truly presents a risk, and that that  
24      can be demonstrated by sound scientific principles.

25              We understand, too, that there are  
26      differences that can come into play because of

1 different commodities and the way they are processed.

2 Certain commodities come into deliberate  
3 contact with water at late stages, as was mentioned  
4 in the -- by Dr. Gardine, and those products have  
5 different risks associated with them than ones that  
6 are maintained dry throughout their process.

7 We also want to make sure that, when we are  
8 describing a commodity or describing a product, that  
9 we're clear on what we're talking about.

10 And one of the words that kind of sends  
11 chills down my spine is -- every time I hear the  
12 word -- "lettuce" associated with E. coli and other  
13 things like that.

14 Most of the incidents, that we really know  
15 of, that have E. coli associations are truly spring  
16 mix products, which are not representative of the  
17 huge iceberg-romaine lettuce industry that is  
18 represented in this valley.

19 And we want to make sure that regulations  
20 that are put forth for lettuce truly represent  
21 lettuce.

22 I think that that's part of the thing, that  
23 we don't overreact and over-respond, based on  
24 misinterpretation of terms.

25 There is a lot of variety and practices  
26 within the domestic agricultural industry across

1 commodities and across growing areas.

2 The same is also true for imported produce.  
3 I know this isn't the imported or the international  
4 area, but as Dole, I feel I have to say a little  
5 something about imported produce as well.

6 You know, we need to make sure that any  
7 recommendations are based on what is an actual risk,  
8 whether it's imported or domestic products.

9 I guess that's just our main message, is  
10 that we wanted to make sure that the food is safe,  
11 but we want to make sure that we are putting our  
12 focus on areas which are going to give us the biggest  
13 bang for the buck, because it would be really foolish  
14 of us to spend a lot of time and money on products  
15 and areas that really don't present a risk, and then  
16 miss the real key risk areas.

17 We want to make sure that any regulation or  
18 any guidance is not so proscriptive that it causes  
19 unnecessary cost, loss of quality or availability of  
20 a given product. And we just want to make sure that  
21 it's remembered, at all times, that increases in  
22 consumption of fruit and vegetable is still highly  
23 recommended by all the nutritionists and that the  
24 public should even be consuming more fruits and  
25 vegetables than they are right now.

26 With that, I would just like to say I

1 think, you know, we've had a great working  
2 relationship with the California regulatory community  
3 when we worked on the IFPA-WGA guidelines.

4 Bob Stovicek was going to be here to talk,  
5 but he is not here, and I worked on that committee  
6 and I think there are a number of people in this room  
7 that contributed to those guidelines, and I think  
8 that is a demonstration of a really good way to get  
9 some things out and to get information out to the  
10 public, and to the actual people who can make an  
11 influence and affect this.

12 So on that note, I'd like to turn the  
13 program over to Donna Gerren from Boskovich Farms.

14 MS. GERREN: Good afternoon. I'm not  
15 really sure I can add too much to what all the other  
16 speakers have commented on. We all have concerns of  
17 how fast this process is moving, and not having the  
18 research to possibly back up some of the  
19 recommendations.

20 So I'll reemphasize that, to be on the  
21 record. But like I said, I think that, again, this  
22 should just slow down until the appropriate field  
23 research can be done and evaluated to determine if  
24 certain questions have been asked and answered in  
25 this process.

26 When doing the research, possibly

1 scientists may want to address some issues that I  
2 have, with being a grower with Boskovich Farms, that  
3 you know, the irrigation, water issue, the manure;  
4 those things affect growers.

5 And certain things that I think maybe they  
6 should address is, like, what pathogens should we  
7 test for, you know, when we're testing, that they  
8 want us to test for?

9 How often shall we test, and actually what  
10 do we do with this information once we do, you know,  
11 go to these labs and test for these types of  
12 organisms?

13 And in the case of irrigation water, the  
14 terminology of using "potable water" as a source of  
15 irrigation water, or at least knowing your source of  
16 irrigation water, and in many aspects, "potable"  
17 means it's drinkable. That's the definition of  
18 "potable water."

19 And many sources of your irrigation water  
20 will not be considered potable by many water quality  
21 experts because of the fact that they are high in  
22 contaminated contents. But that has nothing to do  
23 with the microbial risk involved in spraying your  
24 crops, so certain issues need to add doctors during  
25 research as well.

26 An issue such as transportation, educating

1 your employees on sanitation and hygiene, I think  
2 some direction with FDA and USDA should be directed  
3 towards educating these groups, helping us with  
4 training programs that will go over certain cultural  
5 differences that I know is -- as development of field  
6 sanitation, in my program, I've had to overcome  
7 things such as, "Well, you know, we don't really want  
8 to wash our hands because it could promote  
9 arthritis."

10 I know that seems kind of strange but,  
11 that's something that I've had to overcome and, you  
12 know, just basically educate our employees.

13 No, this probably will not happen, but you  
14 also have to appease them somewhat and try to find  
15 alternatives to the traditional hand washing sink,  
16 such as using sanitizers that do not use water, just  
17 to make them more at ease.

18 Those types of things need to be thought  
19 about when developing programs and helping us train  
20 our employees, and also, training our buyers, our  
21 purchasing agents, the concern for good safety of  
22 what we're doing, and to buy from people who are  
23 thinking about issues of food safety and trying to do  
24 all they can already.

25 And educating the consumer. There was  
26 mention, too, developing programs to educating



1 consumers. We can do all we can, you know, to reduce  
2 the risk of microbial contamination, and then it  
3 somehow fail at the end of the point-of-sale.

4 So certain issues like that, as well as  
5 transportation. I know when we're inspecting our  
6 trucks, you know, that come in. We have concerns  
7 with back-hauling.

8 Of course we don't say that we shouldn't do  
9 back-hauling because that saves companies money, but  
10 there are concerns of transporting fresh produce,  
11 after they've just transported chickens, or any type  
12 of raw product.

13 Certain research to that may be necessary  
14 to address those types of issues that we have.  
15 Again, I think, you know, California and the growers  
16 and processors and shippers are all doing what they  
17 can to promote food safety, and we do back the  
18 efforts that USDA and FDA are doing in promoting good  
19 agricultural practices and manufacturing practices,  
20 but I think we should slow down and address some of  
21 these issues and realize that we do have the safest  
22 food supply in the world.

23 MR. GARDINE: Donna, may I ask a few  
24 questions, and I would ask Dr. Vanderveen and Joyce  
25 to comment further.

26 You brought up a number of really good

1 points, and I think we may want to get into  
2 discussion about them.

3 You mentioned the research needs about what  
4 to test for in water? I believe there is a  
5 recommendation in the guidance that -- while we don't  
6 give a number, we suggest that, since we are worried  
7 about people becoming ill through fecal  
8 contamination, an overall account of E. coli might be  
9 the best way to go, rather than looking for specific  
10 pathogens, but do you really want us to go out with  
11 numbers which then can become contractual obligations  
12 for you?

13 MS. GERREN: No. But some type of -- but  
14 E. coli that's an indication of fecal contamination,  
15 but generally that's an indicator of recent  
16 contamination. So that brings up the point of how  
17 often do we test?

18 Do we continue to test every two weeks,  
19 every month, every three months, every six months?  
20 What is possible?

21 MR. GARDINE: You know, we give some very  
22 broad suggestions in the guidance document about how  
23 often to test. A lot depends on your water supply,  
24 et cetera, what your source of water is.

25 But I just want to stress, and perhaps  
26 other people can comment on it, if we start giving

1 more detailed numbers, is that really what the  
2 industry would want to work with?

3 And perhaps you --

4 MS. GERREN: No, I don't think that's, you  
5 know, what we want. We don't want specifics, but --  
6 however, we do think that there should be some  
7 research in -- basically in seeing, is E. coli, you  
8 know, truly what we should be testing for?

9 Cyclospora is not a situation where it  
10 causes -- they think it might have been the  
11 irrigation water with the Guatemalan raspberries, but  
12 they're not sure because, you know, you can't --  
13 Cyclospora as a research is just not there to  
14 identify that.

15 So, you know, we can't really go into your  
16 testing lab and say, "Okay, we want to test for  
17 Cyclospora."

18 We can't do that. That's the kind of  
19 concerns I have about, you know, the -- the source of  
20 whatever, and, yes, I realize that this document is  
21 more of an examination of our processes and our  
22 practices, and it does, you know, make us examine  
23 what we're doing, but I think there needs to be some  
24 more empirical data out there, and field research,  
25 you know, specific field research, not just from  
26 academia -- I'm from academia recently, so I know the

1 test-tube method is how you start out, but I think  
2 you should continue that and expand, and do more  
3 practical research before guidance can be actually  
4 given.

5 MR. GARDINE: Thank you very much.

6 MS. GERREN: Thank you. I'd like to  
7 introduce Rene Forbes, another grower.

8 MS. FORBES: Thank you for holding this  
9 meeting. I hope and trust that you all will listen  
10 to what is said here today.

11 My name is Rene Forbes, and I am a farmer  
12 in West Fresno County, California. I'm here to speak  
13 just for myself, and not for anyone or group that I  
14 may belong to. I'm unhappy with the public's  
15 emotional fear of the safety of food growing in  
16 America.

17 As a farmer, I do everything I can to  
18 ensure the safety of food grown within my sphere of  
19 influence. I am proud of the ability of the American  
20 farmer to supply safe and nutritious food to our  
21 consumers, and will work with you in our development  
22 of voluntary guidelines for good practices versus  
23 regulations in our industry.

24 Remember that, for any guidelines to be  
25 functional and effective, they must be practical and  
26 economical. The best farm practices are developed by

1 processors and producers, not regulatory agencies. I  
2 am worried that the government recommendations will  
3 soon become mandatory guidelines or prescriptive  
4 requirements.

5 I suggest the following:

6 One, that USDA be the designated lead  
7 agency in these guidelines to food safety. It will  
8 result in less conflict and misunderstanding due to  
9 USDA's better understanding of agriculture.

10 Two, that the guidelines you develop be  
11 administered through the State Department of  
12 Agriculture who are familiar with their State's  
13 production and marketing variations with Federal --  
14 variations versus Federal bureaucracy.

15 I think you have heard here today a couple  
16 of the people from the State and USDA, and I think  
17 you all understand what I mean by that.

18 Number 3, the guidelines should be as  
19 short, simple and as general as possible, and again,  
20 voluntary.

21 We have here the California Department of  
22 Food and Agriculture Worker Safety Regulations,  
23 General Industry Safety Regulations, SB 198, Hazard  
24 Communication.

25 Many California code of regulations to keep  
26 our industry safely producing safe, healthy food as

1 much as possible, and more than covers field  
2 sanitation, et cetera. No, commodity-specific  
3 guidance is also not necessary.

4 No Hazard Analysis and Critical Control  
5 Point program is necessary. It would be another  
6 unjust burden put on our food-producing industry when  
7 is the above-mentioned system is working well in  
8 California. I do not need another regulatory  
9 program.

10 Four, all guidelines should be based on  
11 sound science and reasonable knowledge facts, based  
12 upon actual risk, as you've heard earlier today.

13 I may repeat a lot of what has already been  
14 said.

15 The lead agencies should work with the  
16 Federal and State Game Wildlife Agencies to allow  
17 farmers to remove or distract unwanted animals from  
18 fields. Animals are not allowed into a crop before  
19 harvest, but it is a problem sometimes with unwanted  
20 wildlife. The Endangered Species Act inhibits  
21 growers from any intervening with animals on your  
22 crop.

23 Number 6, manure and urban sewage sludge is  
24 being handled and applied safely, accurately and  
25 effectively in California by conventional farmers.  
26 Personally, I use manure and do so in a very safe

1 manner.

2 On this time frame of composting, as a  
3 farmer, when we use manure, you must have it  
4 decomposed for a certain time because we have seeds  
5 in it. When an animal eats their grasses and things  
6 like that, their food supply has seeds in it, and as  
7 a farmer, you do not take raw sewage -- I mean, raw  
8 manure and put it on your field because then you are  
9 going to have a lot of weed problems.

10 So what you do is, you let it decompose for  
11 a long period of time and then you put it on your  
12 field, and you don't put it on the day or week before  
13 you are going to harvest that crop.

14 In my area, I've never seen any of those  
15 things done. So I believe that it's being done in a  
16 very safe manner.

17 I also believe that urban sewage is highly  
18 regulated in use and testing on the farm. I don't  
19 think any raw or municipal sewage is allowed on a  
20 food crop in California.

21 As far as I know, any that is used is used  
22 on a non-food crop like cotton, and there is a couple  
23 of years before you can plant back to any  
24 food-producing crop that would be edible.

25 I may be wrong, but I believe that we have  
26 great people around here with USDA who can answer

1       that specifically.

2               Number 7, my irrigation system is drip, so  
3       I use as little and controlled water as possible. It  
4       goes through filters and a system routinely flushed  
5       with chlorine to prevent microbiological  
6       contamination of the drip system.

7               My source of water is Westland Water  
8       District, and the water is tested randomly in  
9       different locations throughout the district. I am  
10      kept informed on the state of my water supply  
11      monthly. My water source is open and I have good  
12      quality. I am unable to use ground water on my farm.  
13      I've heard earlier about well water. People think  
14      that's the best.

15              Well, well water in my area will kill all  
16      the plants, because the salt in it is so high and  
17      it's so deep that, if you could afford to go and pump  
18      the water, then you couldn't afford to use it because  
19      your ground will become uninhabitable for any plant  
20      life, so you would not raise any crops.

21              So we have to buy our water from the  
22      government, and it travels many miles in open canals,  
23      but it is good water and we have evidence of it.  
24      It's been good. We have no negative microbiological  
25      contaminants in it in our history.

26              So I feel good that my water source is open



1       -- I already said that.

2               I feel that the source, testing, control  
3 and use of water is safe in growing my crops, so  
4 irrigation guidelines are not really necessary.

5               What I need is better media communication  
6 between the USDA and FDA and other government  
7 agencies, so that fear is not fed to the public due  
8 to lack of science-based government response to media  
9 hysteria.

10              In the initiative the President asks for  
11 better communication. We need a better network for  
12 detecting disease and outbreaks to enhance  
13 communication about these outbreaks to the  
14 appropriate agencies.

15              You spoke here earlier today giving  
16 examples of things like that, so I'm looking towards  
17 the Center of Disease Control that should provide  
18 resources to States to increase their response  
19 capabilities so that more accurate information is  
20 given to the media, which is then distributed to the  
21 public, so we can try to eliminate these big crop  
22 disasters that have happened for crops that have not  
23 even been poisonous or defective to the public, and  
24 yet the public no longer buys them as a result.

25              I encourage implementation and improvement  
26 of irradiation and more development of safe food

1 processes. Something that has been discussed and  
2 it's not in here, but I'm going to bring it up, is I  
3 believe that the recall authority should remain  
4 voluntary on the private side, not a government  
5 power.

6 I feel that it's been said earlier about  
7 how growers and processors and people -- market our  
8 agricultural products. They do it because -- for a  
9 lot of reasons, but mainly you have to be -- it's  
10 safe.

11 If you are going to be selling, like the  
12 beef, the hamburgers were supposed to be tainted with  
13 E. coli. The government did not have to step in and  
14 ask for it to be recalled.

15 At no incidence that I can recall -- I may  
16 be wrong, but that I can recall, has the government  
17 had to go in and force a processor or marketer to  
18 recall a product, because you are in business to  
19 provide good product, and if you have bad product out  
20 there, you want it pulled as soon as possible.

21 So I do not want to see another government  
22 involvement. I think that private industry is  
23 responsible enough to take care of it themselves.

24 I do not think haste is necessary in  
25 developing these guidelines.

26 I agree with President Clinton when he said

1 our food safety system is the strongest in the world,  
2 but I believe, if it isn't broke, don't be in a rush  
3 to fix it.

4 You appear to be listening and learning  
5 from these hearings, but I am concerned that these --  
6 this committee's draft will be overruled by someone  
7 else who has a different agenda, and the guidelines  
8 will not be practical and user-friendly.

9 If the President doesn't feel agriculture  
10 is doing enough in producing safe food, then I wish  
11 he would allocate more money for enforcement of  
12 regulations already established, versus creating new  
13 ones. Use the carrots versus hammers, such as  
14 penalties and prosecution to achieve good goals.

15 I'd like to close with just a little short  
16 story, because I want you to all understand that  
17 farmers are concerned about food safety, and I am  
18 specifically, personally, because I travel and I've  
19 been to China, and I've been where I go into a room  
20 and go to the bathroom.

21 It goes through a slit in the floor. Then  
22 walk down one flight of stairs, and outside, see a  
23 young man with a shovel, taking what had just fell  
24 out of the hole in the floor, and putting it in the  
25 back of a cart that is attached to a burro and that  
26 burro walk to a field that's not far from the house,

1 and shovel it onto produce that's not far from  
2 harvest.

3 I personally have seen this. I have  
4 personally walked along the street and bought fruits  
5 and vegetables off of the street in China and eaten  
6 it. I had a blood test done before I took this trip  
7 to China and I have AB RH-negative blood. I was a  
8 donor.

9 Two weeks before I left, I donated blood.  
10 Two weeks after I returned from China and had a test  
11 again, my blood was contaminated with Hepatitis. I  
12 was fortunate. I did not come down with the  
13 Hepatitis in the symptoms, but I am no longer a blood  
14 donor. That is from eating unsafe food in China.

15 Now, in America, I can go to lunch like I  
16 did today, and eat fruits and vegetables. I can walk  
17 on the street and buy and feel very safe. I have  
18 total confidence and belief in our food supply safety  
19 in America, and I wish more people did so, too.

20 DR. ZAWEL: I'll introduce myself. I'm  
21 Stacey Zawel with the United Fresh Fruit and  
22 Vegetable Association.

23 What I'd like to do, actually, before I  
24 even begin making comments, is address the question,  
25 Tom, that you asked of Donna, and I actually -- I'm  
26 concerned about any misinterpretation, and I want to

1 take the opportunity to just emphasize what Donna  
2 said, and that is that, we're not looking for more  
3 numbers, and the reason we're not looking for more  
4 numbers is because we know that what we need is  
5 research.

6 And so we certainly encourage any research  
7 to be developed to indicate what is the indicator  
8 organism that should be used and what is the  
9 level of that indicator organism might be for a  
10 microbiological contamination might be that would  
11 suggest a public health risk.

12 (Whereupon, the stenograph machine of the  
13 Court Reporter having experienced an electronic  
14 failure, and a brief recess was taken between 2:15  
15 and 2:19 p.m.)

16 DR. ZAWEL: Okay. I'm going to get rolling  
17 here. Again, I'm Stacey Zawel with the United Fresh  
18 Fruit and Vegetable Association.

19 For those of you who don't know, I know  
20 some of you are our members, but for those of you who  
21 aren't familiar with United, we represent growers,  
22 packers, shippers, wholesalers, brokers, as well as  
23 processors and industry suppliers throughout the  
24 United States and abroad..

25 I wanted to again start where -- actually  
26 where I started previously, and that is to emphasize

1 the issue about numbers and just, does the industry  
2 really want numbers?

3 No, we don't want numbers. Only if they  
4 are based on science, and at this point, we do not  
5 have the appropriate numbers to -- we don't have the  
6 appropriate science to dictate what those numbers  
7 should be or meaningful indicator levels, or what  
8 that indicator level might be for microbiological  
9 contamination that would have a public health risk.  
10 Therefore, at this point, I would say that we should  
11 have research.

12 I have been given the job of clean-up, and  
13 I guess this is somewhat appropriate, especially  
14 since I have had both what I call the opportunity and  
15 the challenge to go to all of the previous meetings,  
16 and will also be in Oregon.

17 So what I want to do is provide a summary  
18 of all of the meetings, and basically, it's probably  
19 extremely repetitious of what's gone on today, and I  
20 think we have gotten some have very beneficial input  
21 from this region, and it certainly will minimize the  
22 comments in the other regions.

23 But for the benefit of the record, and for  
24 all of you, I do want to summarize some of the  
25 comments from the other meetings, as well as this  
26 one.

1                   However, keep in mind that this is not  
2 all-inclusive of everything that was said.

3                   The one thing before I do begin, I believe  
4 I have 12 points that I would like to make, but  
5 overriding all that is the emphasis that the industry  
6 is very concerned about continuing along to assure  
7 the safety of our products.

8                   I will begin with Number 1.

9                   That is, we urge you to slow down the  
10 process. You've heard that over and over today.  
11 We heard it at other meetings. The current pace  
12 threatens to marginalize the produce industry's  
13 participation. It ignores the complexity of our  
14 industry, and disregards scientific uncertainty  
15 behind microbiological food safety issues.

16                   A second recommendation is that you go to  
17 the administration, you communicate the challenges  
18 that you have -- that have been communicated to you  
19 and that, hopefully, are very obvious to you, in the  
20 course of having these meetings, and request that  
21 this process slow down, saying in fact that you do  
22 not want to sacrifice doing it right for doing it  
23 fast.

24                   And certainly, in this, we encourage you to  
25 make -- to continue to have more visits throughout  
26 the country. Additional grass-roots meetings and

1 field tours are an absolute necessity, especially the  
2 field-tour activity, not only additional meetings in  
3 California. Certainly we need an additional meeting  
4 in Texas in a more opportune area to increase grower  
5 input into that region, and other areas as well.

6 And I think that, throughout the meetings  
7 in all of these different regions throughout the  
8 United States, you have gotten multiple offers to  
9 facilitate that for you.

10 We also continue to urge you not to spend  
11 your energy on developing commodity-specific  
12 documents, and in fact, we have been involved with 20  
13 other produce organizations in the development of an  
14 industry-wide guidance, and in this industry-wide  
15 guidance, it states a very important intention, and I  
16 also recognize and United was also involved in the  
17 IFPA-WGA effort, and I know the intention of that  
18 document is to do the same, and that is to serve as a  
19 catalyst for efforts across the produce industry to  
20 develop, refine and implement measures to enhance  
21 assurances of food safety.

22 So by saying that we don't want  
23 commodity-specific guidance does not mean that the  
24 industry does not want to do anything, but there are  
25 tremendous efforts around the country right now,  
26 pursuing that, and that's where it belongs.



1           It is unclear to me how development of  
2 commodity-specific guidance is going to add value.  
3 Instead, what will add value and what will provide  
4 for effective public health measures is to spend your  
5 resources in a well-thought-out outreach and  
6 education program, and that focuses on educating the  
7 industry in appropriate areas.

8           The fifth point I'd like to make is that  
9 any guidance that is developed must refer to any  
10 State, regional and local regulations currently in  
11 place governing water use, governing manure and bile  
12 salts and governing wildlife.

13           At every single region that we went to,  
14 there was emphasis that there are strict regulations  
15 on water use. Some people recommend in certain  
16 regions to increase the use of manure, to use  
17 bio-solids and very interestingly, and it was  
18 repeated today, and there are great restrictions on  
19 the ability for any one grower to restrict the  
20 wildlife.

21           In New York, for instance, they cannot keep  
22 deer out of their fields. It is not allowed by the  
23 wildlife people who oversee wildlife in that region.  
24 And in Florida, there was an interesting story where  
25 a citrus grower had a bear and her cubs in his field.

26           He was forbidden to do anything about it,

1 especially since the bear had cubs. So he's got to  
2 live with that and you certainly hope it's not eating  
3 the crop.

4 The sixth point is something that is very  
5 important and was brought up, and that is, to make  
6 sure to put the sanitizers and disinfectants and  
7 other technologies on a fast track for approval.

8 And, in fact, this is right in line with  
9 what the National Advisory Committee on  
10 microbiological criteria for foods, recommended about  
11 a month ago, and that is that the committee  
12 recommends that FDA, USDA and EPA should review their  
13 approval processes for technologies being developed  
14 that address public health concerns associated with  
15 fresh produce and measures to permit rapid approvals  
16 for new technologies, and that new uses of existing  
17 technologies should be identified and implemented.

18 My seventh point has to do with positive  
19 lot identification. This is a very easy thing, from  
20 a regulations' standpoint, to request of the industry.

21 To request specific pieces of information,  
22 get it put in place at the grower-shipper level.  
23 However, at that point, you lose complete control,  
24 and that information must be maintained throughout  
25 this process.

26 So, rather than dealing with this issue on

1 a segment-by-segment basis, meaning from the  
2 grower-packer-shipper, up through transportation, up  
3 through terminal markets, up through retail and  
4 restaurants, what I recommend -- the industry is  
5 already doing this, for one, and we're working  
6 proactively with our industry partners to address  
7 this issue, and certainly, I recommend that that  
8 remain in that area.

9           However, if you continue to be compelled to  
10 do so, we encourage you to follow that model, to work  
11 with all of us together. That is the only way that  
12 we are going to address the challenges of an overall  
13 trace-back system to help, not only the  
14 epidemiologist in this very challenging area, but  
15 also to help the industry.

16           My eight point is, monitoring worker health  
17 is very, very difficult challenge, not only from an  
18 industry standpoint, but also from the standpoint of  
19 those who represent those workers.

20           It was stated many times by -- in many of  
21 the different areas, for instance, by Extension  
22 agencies, the industry and the UFW, that privacy  
23 rights are very, very important, and the workers are  
24 going to be afraid to tell you if they're ill, and  
25 certainly, all they've got to do is tell you once  
26 that they have got diarrhea, and you send them home,

1 they are never going to tell you again. So it's a  
2 very, very difficult issue to deal with.

3 My ninth point is that we appreciate very  
4 much that FDA is developing guidance and not  
5 regulation.

6 As a matter of fact, at the first meeting  
7 in Michigan, the FDA representative from Chicago  
8 said, "Well, we have too many rules already that we  
9 don't enforce; why should we make another one?"

10 So I -- I liked that comment so -- and I  
11 think it is a case of a new paradigm. We have a lot  
12 of -- we have a good model to shoot for, and I think  
13 that we are moving in that direction.

14 However, something that was brought up,  
15 over and over again, was that this will become,  
16 de facto, regulation, and it's going to be very easy  
17 to misinterpret some of the intentions that are in  
18 here, and I think that there have been many  
19 demonstrations throughout these meetings as to what  
20 those are.

21 I hope those are clear to you and I do hope  
22 that the industry provides in writing some of those  
23 specific things, and I know United will, on behalf of  
24 the industry, but recognize that that is going to  
25 happen and that provides a basis for a lot of the  
26 reaction to some of the content.

1           My tenth point is science, science,  
2 science. We have to base recommendations on science.  
3 Issuing any guidance that suggests impractical  
4 recommendations that are not based on sound science  
5 or reasonable information will be counterproductive  
6 and ineffective.

7           And in fact, the National Advisory  
8 Committee again recommended a month ago, in their  
9 list of recommendations, the following:

10           That many GAPs exist in our understanding  
11 of produce as a vehicle for food-borne disease, as  
12 well as intervention strategies to prevent, eliminate  
13 or reduce pathogens that are present, if they are  
14 present.

15           And therefore the committee recommends that  
16 research be initiated as soon as practically possible  
17 on many of the issues, and they did make -- have a  
18 list of some of their recommendations.

19           My eleventh point is that, as this  
20 initiative moves forward, and contemplates a means to  
21 effect standards in countries importing to the U.S.  
22 market, it must be done so in a manner that is  
23 consistent with free-trade principles, and I hope  
24 that you did get a tremendous amount of feedback on  
25 the international meeting on Monday.

26           And my twelfth, and last point, is one that

1 we have heard over and over. We continue to stress,  
2 and I know public health officials feel very strongly  
3 about this as well, and that is, throughout all of  
4 our discussions, whether it's industry, government,  
5 consumers, and -- anybody that is involved through  
6 discussions, documents, interviews, regarding  
7 microbiological food safety risks associated with the  
8 consumption of fresh fruit and vegetables, we must  
9 continue to clearly state the importance of  
10 increasing knowledge of the consumer, because we are  
11 at a time when processed food consumption is on the  
12 rise, along with the rise in chronic diseases, such  
13 as cancer and heart disease.

14 An overwhelming number of scientific  
15 studies indicate the consumption of fresh fruit and  
16 vegetables, anywhere from five to ten servings a day,  
17 can decrease one's risk of many of these diseases,  
18 and therefore none of us can jeopardize the public's  
19 health, but instead encourage increased consumption  
20 of fresh fruits and vegetables, and as Nancy said,  
21 "We're on our way there, but we've got a long way to  
22 go," and so we all need to provide that message  
23 continually in all of our discussions, and make sure  
24 that this guidance does not impact that wrongly.

25 With that, I will end and invite you to ask  
26 any questions of anybody up here.

1                   Thanks.

2                   MR. GARDINE: I do believe, before we go  
3 forward to open it up to general questions, there is  
4 a point I must repeat what was said this morning.

5                   The President's initiative is, "Food safety  
6 from farm to table."

7                   Many of the speakers here raise the concern  
8 on the part of industry, on the part of the grower  
9 community, that you are being fingered as the  
10 culprits, and the vast majority of governmental  
11 resources are going to fall on you as the only way to  
12 limit illnesses associated with fresh fruits and  
13 vegetables in the microbiological area.

14                  One, we do agree with you, that there a  
15 large part of the problem is in handling after it  
16 leaves the farm.

17                  That is why the President's overall  
18 initiative and the work of FDA and USDA includes a  
19 large component for consumer outreach, includes a  
20 large component for retail education, in terms of our  
21 retail food code improvements and that increased  
22 outreach.

23                  We do understand that. We understand that  
24 very, very well. I wanted to make that clear to  
25 everybody.

26                  It is just that, rather than waste another

1 hour of this day with government people getting up in  
2 front of you and telling you about our stop-bac  
3 education program for consumers, and -- what is it--  
4 "Fight-bac" -- excuse me, our retail food code and  
5 what we've been doing for years with the retail  
6 industry.

7 That was not the intent of this meeting.  
8 Programs working with your trade organizations and  
9 through the State agencies, we can get the words --  
10 find a way, and we'll have to think about that, to  
11 get the word to you as growers that we are doing  
12 this.

13 It is a vast effort on our part, and  
14 certainly we see what we're doing here as only one  
15 part. If we are going to make progress in this area,  
16 to maintain the already good record of safety, of  
17 safety of produce in the United States, that it is a  
18 holistic approach from farm to table.

19 Unfortunately, you are the farm. So that  
20 is one part of it, and that is basically one point I  
21 wanted to make, and the other point that I would ask  
22 you to think about, and I'm sure many of you will  
23 comment on this, is, we are hearing a great deal here  
24 about what California growers are doing, and it's  
25 impressive, and it's substantial, and I believe, as  
26 we said before, we borrowed heavily from it.



1           We want to work with you more on it, but,  
2   does the guidance document that we've put together --  
3   is it doable, is it practical? Is it workable? Does  
4   it have a real effect? Because this is a big country  
5   -- while you might think California is most of it,  
6   there are other parts of this country, and, once  
7   again, more and more of our produce is coming from  
8   foreign suppliers.

9           We have no reason to believe that their  
10   product is any less safe, that their produce is any  
11   less safe, but perhaps this guidance, if it is based  
12   on the best current science, which is good science --  
13   if it is doable and practical, is this advice that  
14   perhaps you might be, in California, a step ahead of  
15   us.

16           You might feel that you are, but is this  
17   something that has utility as a base point around the  
18   country, and for us to work with our trading partners  
19   on with, so please speak about that as you are giving  
20   general comments.

21           California, as much as you might think  
22   differently, is not the world. Thank you.

23           MR. VANDERVEEN: First, I'd like to thank  
24   you very much for your presentations. It's been very  
25   helpful. A couple of things that I think that I  
26   should try to bring you up to date on.

1           Testing was mentioned a couple of times,  
2   and I'm sure you understand this, but just to make  
3   sure that I didn't misunderstand you, there is no way  
4   that we're ever going to assure the food safety --  
5   the safety of produce by testing.

6           Our chances of finding organisms in any  
7   commodity and protect the public health on the basis  
8   of testing is -- we're talking about, you know -- if  
9   we were to do 90-percent tests, it might start having  
10  some effect, but otherwise, it's a hopeless cause.

11          Microorganisms don't distribute themselves  
12  uniformly in all pieces of produce, and so, as a  
13  consequence, it -- it's a problem that just isn't  
14  going to happen.

15          If you don't believe it, just look at our  
16  trace-backs in the juice problem that we had. We  
17  were able to find the exact organism that caused the  
18  problem, and in only one of how many thousands of  
19  samples we analyzed?

20          It is clearly not a way in which you are  
21  going to -- so we are not going to -- we can't give  
22  guidance on how to test for these organisms. I'm not  
23  suggesting that testing shouldn't be part of a QA  
24  program.

25          I am suggesting that we can't rely on it to  
26  make sure the food supply is safe.

1           The next item is transportation, and I  
2 agree with you entirely, that you -- you are at the  
3 mercy of the transportation industry. And what I  
4 want to talk about there is the fact that we are  
5 determined, and we have had meetings with the  
6 transportation industry and carried your message  
7 previously, that they have to do something about this  
8 issue.

9           Now, the history of that is difficult. The  
10 Congress, including the Vice President, when he was  
11 in the Senate, gave the authority for dealing with  
12 issue of food safety and transportation to the  
13 Department of Transportation.

14           Unfortunately, they do not have the  
15 resources, nor the interest in dealing with that, and  
16 the foods -- what is it called -- Sanitation  
17 Transportation Act of 1990, has -- they did put out a  
18 proposal but that was the end of it. They don't have  
19 anyone working on it at the present time.

20           Recently, the administration suggested that  
21 authority be transferred to the Department of  
22 Agriculture and to the Food and Drug Administration  
23 for respective areas.

24           We have looked at our authority and feel,  
25 under the Public Health Service Act, we might be able  
26 to put out a very simple regulation to help you in

1 that regard, and that regulation would do just the  
2 following:

3 It would say to anyone who is going to be a  
4 transporter of -- offer their services for  
5 transportation, that they must tell what was their  
6 last three cargo hauls, if you will, in their  
7 vehicle, train, truck, whatever, and how did they  
8 clean the vehicle after those transportation.

9 We feel that that type of simple  
10 regulation, and then they would have to tell the  
11 shipper what that truck was used for, or what that  
12 truck or vehicle was used for after the last three  
13 opportunities, and leave it up to the shipper to  
14 decide whether it was adequate for them to send their  
15 goods.

16 If you think that's a reasonable approach,  
17 we would like support in that when the time comes,  
18 and we -- but we are looking at the transportation  
19 issue.

20 Unfortunately, we don't have the authority  
21 to do all we'd like to do in that general area. We  
22 may get it some day.

23 I think we heard you loud and clear about  
24 "Slow down," but I would just have one comment.

25 If you look at our record and how well we  
26 have kept to our time lines, you wouldn't be terribly

1 nervous, and we apologize for that, but you know  
2 there is always another crisis that takes people off  
3 of a project like this and puts them on the project  
4 -- the crisis of the day, and although -- let's look  
5 at it from the other standpoint, one never gets  
6 anything done if they don't try to put, and build in,  
7 time lines.

8 I'm sure you'll have plenty of time to deal  
9 with this, and I'm sure there will be some  
10 stretch-out, but that's my opinion and not the  
11 official agency policy.

12 MR. NELSON: She wants me to read  
13 something. I have to put my glasses back on. She's  
14 got me. We do have a web site. It's fightback.org.

15 -- www --

16 No, they know that.

17 MR. McINERNEY: Not everything is preceded  
18 by www.

19 MR. NELSON: Mine is. We'd like all your  
20 feedback now, so here is your chance to ask questions  
21 and put your feedback into the document, and so --

22 MR. WINNER: My name is Don Winner  
23 (phonetic), and we are a -- we are a fresh juice  
24 processor.

25 We don't grow it, but we do a lot of fresh  
26 fruit and vegetables. So I'd like to thank you for

1 the opportunity to air our comments. I think the  
2 forum is really good.

3 One of the things, I guess a key factor for  
4 us, being a fresh processor is the -- we really look  
5 at how the fruit is handled, and also how it's grown,  
6 and I think that's a real key factor for us, you  
7 know, because we are pulling in a lot of fruit, and  
8 we don't know how it's been handled. And I think the  
9 -- with our business, it's real critical. It's real  
10 critical to have sound good fruit and vegetables.

11 Most fresh processors either have  
12 implemented or are in the process of implementing a  
13 comprehensive food safety program, and as a  
14 processor, we at least advocate the idea of HACCP  
15 process because we currently have one in use right  
16 now, along with our GMPs, and sanitation procedures,  
17 which we have on a regular basis. They are monitored  
18 from the outside, a third party.

19 So, I think what you need, about the HACCP  
20 part of it is, that it tends to be unique toward our  
21 operation, and what's critical to our operation on a  
22 day-to-day basis, and yet some of it has to do with  
23 transportation, in monitoring temperatures and things  
24 like that, that goes into our vehicles.

25 So -- and another key factor that was  
26 brought up earlier is the -- for our -- as a fresh

1 processor, the trace-back of produce from the  
2 processor to the field.

3 We get a lot of product that we use in our  
4 manufacturing that we have lot numbers where we can  
5 trace it. We have some vineyards that will supply us  
6 with that information, but a vast majority of the  
7 product, we have no idea where they come from. We  
8 usually get a packing house or a ship location. So  
9 we don't know where the produce comes from, or the  
10 fruit or vegetables.

11 MR. GARDINE: Before you go on, can you  
12 demand that?

13 MR. WINNER: We have done that, in the  
14 past, and there are a lot of vineyards I've turned  
15 down because of the quality of the fruit. I've had  
16 to reject some fruit -- so, yeah, that does -- we can  
17 demand it, but economics sometimes put us in an  
18 awfully tight situation --

19 MR. GARDINE: I do understand that.

20 MR. WINNER: -- because we are a company  
21 with a bottom line.

22 MR. GARDINE: But it's something that you  
23 can work with your suppliers to encourage to the  
24 extent possible when you have options.

25 MR. WINNER: Right. As a person in the  
26 middle between the grower and the public, we really

1 feel that it's important to know where that produce  
2 comes from. And you know, a lot of our customers,  
3 big customers, ask us, you know, "What kind of  
4 processors do you have? Where does it come from?"

5 In some instances, we don't know.

6 And I think we know that the produce  
7 industry takes it real seriously, the responsibility  
8 it has in minimizing the potential of microbiological  
9 hazards in growing and packing shipping products.

10 I think food safety should be, and I think  
11 everyone agrees, safety is the Number 1 concern, and  
12 I feel that the HACCP or trace-back program would  
13 help ensure the safety of products and also products  
14 to the consumer, whether they are fresh produce or  
15 packaged goods, and result in repeat business and  
16 also improve profitability, because I think what we  
17 have found is the better quality of product we have.

18 Obviously, we're in more of a premium  
19 business where we can -- we can probably charge a  
20 little bit more, but that's the idea behind when you  
21 look at some of our customers, what they demand.

22 You know, they are really looking for high  
23 quality products, when it comes to fresh juices, and  
24 -- but I just wanted to get that across for the  
25 record there.

26 MR. NELSON: Thank you.



1 DR. TENZER: I would like to --

2 MR. GARDINE: Please identify yourself.

3 MR. TENZER: My name is Abe Tenzer, and I  
4 am from Bonagra Technologies and Services.

5 Our company has been working very hard for  
6 the past seven years to increase the efficacy of  
7 chlorine as a sanitizer because we all know and  
8 realize that many of the people that use chlorine in  
9 our industry don't really understand what they are  
10 testing for, don't even know how to spell my  
11 hydrochloric acid, and therefore don't understand  
12 what they get in the way of sanitation.

13 Seven years ago, we developed this process,  
14 went to toxicity tests, and followed the  
15 recommendation of CFR 173.315.

16 And today, I am very, very happy to report  
17 to you that, after completing seven years of studies  
18 and spending close to two million dollars, we have  
19 developed a very, very unique system for sanitation,  
20 which relies, Number 1, on the chlorine potentiator,  
21 which is our potentiator to align the chlorine to act  
22 in the pH range between 6 and 10 rather than six and  
23 7 and a half.

24 We have developed a computerized monitoring  
25 and injection system, that follows the hydrochloric  
26 acid's concentration by the use of a proprietary ORP

1 sensor, and the most important thing, we are helping  
2 our clients to safeguard their future interests, both  
3 from a professional point of view and legally.

4 Every batch that goes through our system is  
5 marked and every batch is being evaluated by the  
6 machine by our computerized system, every 12 seconds,  
7 and we have records of pH, temperature, ORP.

8 In addition to that, we have also arranged  
9 for samples to be taken every week of each one of the  
10 commodities that are coming into the packing house  
11 and are being washed in our system, to verify the  
12 efficacy in terms of standard plate counts, in terms  
13 of E. coli -- and in terms of E. Coli 0157:H7.

14 We have also initiated a program on full  
15 commodities, apples -- actually, five. Apples, baby  
16 carrots, green peppers, tomatoes and citrus to help  
17 out with the situation that the gentleman, the juice  
18 man, mentioned before, and we know what goes into our  
19 production line, and more importantly, we know what  
20 goes out from our production line.

21 And the fact is that we are capable of  
22 reducing E. Coli 0157:H7 as well as pathogen to the  
23 extent of over five lots.

24 This technology is available, and I'll be  
25 very, very, happy to give my cards to the other  
26 people here in the room, or wherever they are.

1           Our web cite is [www.bonagra.com](http://www.bonagra.com), and the  
2 fact is that, in most of the industries, they have a  
3 killing stage, a killing phase, and therefore they  
4 are, quote, unquote, "secure."

5           Even though they still have botulism in the  
6 canning industry, and many other places, but for the  
7 first time we have now a killing phase for fresh  
8 produce at temperatures up to 100 degrees Fahrenheit,  
9 tested and proven over the past seven years, and  
10 continuously being challenged and tested by our  
11 clients.

12           Thank you.

13           MS. DODGE: Would it be possible for me to  
14 come up there and put my papers on the podium?

15           MR. NELSON: Yes.

16           MS. DODGE: My name is Elaine Dodge and I'm  
17 the Executive Director of STOP, Safe Tables Our  
18 Priority. STOP is a consumer-advocacy organization  
19 made up of primarily victims and their friends and  
20 family -- victims of food-borne illness.

21           We were founded in 1993 after the  
22 Jack-In-The-Box out-break and since that time, our  
23 membership has grown to include victims of E. coli  
24 from juice and from produce and Salmonella from  
25 produce, and Hepatitis A victims from the frozen  
26 strawberry outbreak.

1                   And I appreciate being able to come up  
2 here and be able to speak to you all, and I have to  
3 confess that it's intimidating because I'm used to  
4 addressing folks in Washington, D.C. where I'm not  
5 the only consumer representative in the room, and  
6 when I come to these State meetings, it's scary  
7 because I realize I'm the only one with this point  
8 of view in the room.

9                   And I wanted to thank you in particular to  
10 invite me to speak up, and in fact to debate with  
11 people here today, and I wanted to remind you all --  
12 all of you in FDA that those of us in the consumer  
13 community need an invitation to an event to be able  
14 to be here, to be able to debate, and we often don't  
15 get included in the invitation or included in the  
16 line-up of speakers.

17                  And I would also make a suggestion for the  
18 future that, if you have a format where you have a  
19 round table, rather than this sort of back-and-forth  
20 addressing system. It becomes more of a dialogue,  
21 rather than sort of a recitation of a -- of points.

22                  The first comment that I wanted to make is  
23 that, as I read the guidance document, I'm concerned  
24 about the ultimate effectiveness of it because, as a  
25 guidance document, and as it being a document, and I  
26 as a lawyer know that recommendations don't have the

1 force and effect of law like regulations do.

2 I also, having worked in food safety for  
3 the last eight or nine years, know that, as many  
4 people today have exemplified, that most of the folks  
5 in the industry are conscientious people who put out  
6 a clean and safe product.

7 But there are people in the industry  
8 that don't operate that way, and that's who the  
9 regulations are targeted for, and unless you  
10 have 100-percent compliance with the kinds of  
11 recommendations that are in this guidance and  
12 with regulations, then you have a food safety net  
13 that has holes in it, and that's how people get  
14 injured.

15 My second observation and concern about the  
16 guidance document is that it's not clear what the  
17 goal is. From my point of view, the goal should be  
18 taking steps that are designed to eliminate  
19 microbiological contamination of product, and STOP,  
20 in all the safe food organizations, that I am aware  
21 of, recognize that it's impossible to produce a  
22 sterile raw product.

23 So we understand that raw meat and poultry  
24 has a possibility of being contaminated -- raw  
25 produce, raw juice, raw everything, that there is the  
26 potential for contamination.

1           But I think there is an important  
2           distinction in how you identify -- it's important how  
3           you identify the goal, because it's going to have an  
4           impact on whether or not you reach it.

5           So if the goal, as I read it in this  
6           document, is to reduce microbial contamination, then  
7           you are not going to get as close to the goal, if the  
8           goal is to eliminate microbial contamination, and by  
9           that I don't mean -- well, I would like the goal to  
10          be eliminate microbiological contamination in the end  
11          product, but it's very important that the steps that  
12          you take along the way are aimed at ending microbial  
13          contamination.

14          So in other words, when you are addressing  
15          the issue of water, the goal is to have no microbial  
16          contamination in the water or pathogenic microbial  
17          contamination in the water, and the goal of manure  
18          should be not any microbial contamination, so that  
19          when you apply those products to your produce, there  
20          is a -- it further reduces the likelihood of those  
21          products being contaminated.

22          Another observation I made about this  
23          guidance document that concerns me is the use of the  
24          word "may" versus the word "should."

25          As I see this document, the recommendations  
26          seem benign, and to take relatively modest and mild

1 recommendations and further weaken them by saying,  
2 "Producers and growers may do this," it almost  
3 eviscerates or makes it -- neutralizes it of having  
4 any kind of effectiveness.

5 So I would recommend substituting the  
6 word "may" for "should."

7 Then I would like to address this point  
8 about consumer education. We are a consumer  
9 education organization. We believe in consumer  
10 education. We were instrumental in persuading the  
11 U.S. Department of Agriculture to change their  
12 consumer education message about cooking temperatures  
13 for ground beef from brown in the middle, which was  
14 an incorrect message, to a time temperature  
15 recommendation.

16 I'm looking for guidance from all of you --  
17 no pun intended -- for what you want me to tell my  
18 members, what you want me to tell consumers about  
19 your products.

20 Believe it or not, I've been told that we  
21 should -- our Odwalla apple juice victims should have  
22 known that that juice was a raw product, and we  
23 should have taken it home and boiled it before we  
24 served it to our children, and I can buy your  
25 tomatoes and recommend to our members that you buy  
26 your tomatoes and make spaghetti, but what do I tell

1 people about lettuce and alfalfa sprouts, and what do  
2 I tell people about frozen strawberries?

3 And just for the sake of debate, to respond  
4 to a couple of points that other people have made,  
5 we're big believers in science, and I think that -- I  
6 agree with many of the statements that have been made  
7 today about the lack of scientific basis for some of  
8 these recommendations.

9 Where it stands out in particular is in the  
10 sections under water and the sections under manure,  
11 and our recommendation would be that -- and we've  
12 been through this with raw meat and poultry -- that  
13 you test water for the presence of generic E. coli so  
14 that -- so you see whether or not you have fecal  
15 contamination in the water.

16 It's not to give you information as to the  
17 safety of your product in the end, but it gives you  
18 information about your process, about the safety of  
19 the water that you are using for a variety of  
20 purposes.

21 But generic -- but there is a big debate,  
22 and I don't know if you all are aware of this, within  
23 the meat and poultry community as to the utility of  
24 generic E. coli information, and those of us in the  
25 consumer community advocate pathogen-specific  
26 testing, because that's -- even though it's -- the



1 beef folks are proud to tell me that cooked feces  
2 isn't going to hurt me.

3 Even raw feces with no pathogens isn't  
4 going to hurt me. I don't want to eat cooked feces,  
5 and I don't want to eat irradiated feces, and I don't  
6 want to eat your product with feces on it, and I  
7 certainly don't want -- none -- nobody -- and neither  
8 do you -- wants anyone to get sick from a pathogenic  
9 -- a product contaminated with pathogens.

10 And the same is true with manure. There is  
11 a very difficult -- when I asked you to give me an  
12 example of what you meant by community and cultural  
13 differences, in terms of agricultural treatments, and  
14 you used the example of manure, that's a very --  
15 that's an issue that concerns me.

16 When there is science that shows and it's  
17 reflected in your document, that E. coli 0157:H7 can  
18 last up to 70 days in steer manure and a year in  
19 sheep manure, and then there's folks on the East  
20 Coast who have a growing season of less than 40 days.

21 It doesn't seem to me that the conclusion  
22 is, Well, Jeez, consumers who eat the product that's  
23 grown out of untreated manure in less than 40 days in  
24 the East Coast have to take their chances, as opposed  
25 to people who can -- I mean, I suppose that's one  
26 approach, but along the lines of consumer education,

1 if that's the approach you want to take, then I think  
2 it's incumbent upon the growers in the industry to  
3 provide consumers with information so that they can  
4 evaluate the level of risk and take those chances  
5 themselves, but it's not for you all or the  
6 government to have that information and consumers to  
7 have to literally live or die by the decisions and  
8 the information that you all have.

9 Recall. There is currently recall  
10 legislation before Congress for USDA, and the reason  
11 why consumers have been so concerned about recall for  
12 so many years is not because any meat and poultry  
13 processor or slaughterer hasn't eventually recalled  
14 their product.

15 It's the number of days between the time  
16 that a product has been identified as contaminated  
17 and that negotiations continue between government and  
18 industry, and industry decides that they will  
19 voluntarily recall their product.

20 And in those days, product is distributed  
21 at the retail level. It's purchased, it's taken  
22 home, it's put in the freezer, it's cooked and people  
23 get sick. So it's about timing, not about  
24 compliance.

25 And I guess one last comment I'd like to  
26 make is about irradiation, which you know is a very

1       debatable topic in all of these forum.

2               Irradiation is not a silver bullet, and  
3       within our organization, we're constantly wrestling  
4       with irradiation, "Yes" or "No."

5               One of the things to keep in mind about  
6       irradiation is that it doesn't kill 00 cysts, and it  
7       doesn't destroy the sugar toxins, and --

8               MR. GARDINE:   Hepatitis A.

9               MS. DODGE:   -- and Hepatitis A.

10              A VOICE:   How about B and C?

11              A VOICE:   And the new E variety?

12              MS. DODGE:   Well, so. . .

13              Thank you very much.

14              MR. GARDINE:   I just want to add a few  
15       things here, because I do not want our representative  
16       here from the consumer group to think she is the only  
17       consumer advocate in the room.

18              I think most of us from FDA, USDA, the  
19       State agencies and local agencies and the trade, I  
20       believe -- believe they are consumer advocates here.  
21       I do want to thank you for reminding me that I did  
22       want to say something about recalls, and you did say  
23       it for me.

24              While it might appear that recalls always  
25       get done voluntarily, frequently for someone who has  
26       been there, the time that we think a recall is

1 necessary, and the time that, on occasion, a  
2 processor might agree that the recall is necessary,  
3 does on occasion, in my personal opinion, put the  
4 consumer at risk.

5 And so recall authority is something that I  
6 certainly think appropriate or for regulatory  
7 agencies to have. That is nothing to do with why we  
8 are here but I thought I'd put that on the record,  
9 and I do want to point out, the one concern you  
10 indicated that it appeared to you perhaps that the  
11 regulation didn't seem to be going anywhere, didn't  
12 have an end point.

13 I when we say we all agree, you cannot have  
14 a sterile world, but we do say reduce microbiological  
15 hazards to the extent possible, and what we are  
16 trying to point out there is, within the limit of  
17 science and what we know, and what is doable, you  
18 should reduce, to the extent you can, microbiological  
19 hazards associated with produce, and I personally  
20 thank you for your comments, and we did try to get  
21 the word out to consumer groups and I, like you, are  
22 somewhat concerned that, at some of the earlier  
23 meetings, consumer groups appeared to be  
24 under-reached, and I don't know why.

25 MRS. TENZER: My name is Gail Tenzer, and I  
26 am from Bonagra Technologies. I would like to

1 address Elaine.

2 It's interesting, first of all, that she  
3 brought out the thing about regulation, and what the  
4 end will be, and that it isn't forceful enough in  
5 California.

6 In California, we practically don't have to  
7 worry about it. The market does. This is the most  
8 litigious State in the country, and one of the things  
9 I am constantly telling growers is that, if they take  
10 action against a bug in the field, that they can see,  
11 with a pesticide, and spend the thousands of dollars  
12 that they do, the way they do, if they were totally  
13 devastated by this insect that they can see, the  
14 worst thing that could probably happen to them would  
15 be that they would lose that season and a lot of  
16 money.

17 However, that little invisible bug, in this  
18 country, and particularly in this State, probably  
19 would destroy the company altogether. They would  
20 probably never recover from the class action suits,  
21 and being an attorney, I'm sure you understand.

22 Now, as far as everything else is  
23 concerned, we in the industry are extremely conscious  
24 of the problem because all of us are consumers, too.  
25 My husband is an --

26 A VOICE: Immune compromised?

1 MRS. TENZER: -- immune compromised. I  
2 have an 85-year-old father who cannot afford to get  
3 an infection, at this point, because it would kill  
4 him.

5 I think many of us have either children or  
6 somebody like that, and we're all aware of the fact  
7 that the tomato that we are handling today we  
8 probably will end up consuming, because it will come  
9 back in the form of a salsa, or we're going to buy it  
10 at the local super market and prepare it in a salad,  
11 or something.

12 The problem that we are experiencing right  
13 now is one that is -- has not been that new to the  
14 meat and poultry industry.

15 However, fruits and vegetables are new  
16 vehicles of transmission for these particular  
17 bacteria and microorganisms, because fruits and  
18 vegetables were always considered to be high acid and  
19 therefore safe.

20 The pathogens did not normally survive at a  
21 pH of 4. Now they are surviving at a pH of 2, and  
22 under refrigeration.

23 So we are confronted with, all of a sudden,  
24 trying to scramble very, very quickly with attempting  
25 to do research in areas that we hadn't done before to  
26 deal with a problem that concerns all of us very,

1 very much also.

2 Not just as industry members, not just  
3 because we would like to preserve our businesses, but  
4 also because we're very, very concerned about  
5 preserving the lives of all of our dear ones.

6 So we can't forget that we're consumers  
7 also and I wanted to lay your fears at rest, as far  
8 as how this industry is responding.

9 I have talked to many, many people that I  
10 know. There are many, many people who are concerned.

11 Very often you'll hear that this grower or  
12 that grower, his wife has breast cancer or something,  
13 and they are extremely concerned not to get any  
14 infection because of the medication that they are  
15 taking.

16 So I don't think that any of us that are  
17 working in this industry ever forgets that we're also  
18 buying everything that we are working with.

19 What you could take back to the consumers  
20 is that, Number 1, all we can really talk about is  
21 risk minimization, at this point, first of all,  
22 because we were all caught by surprise.

23 Nobody expected microbes that usually would  
24 only be found in animals to be found, all of a  
25 sudden, on tomatoes or melons or anything of the  
26 sort.

1           It never happened before, and it has  
2   started happening in the last -- oh, decade or so,  
3   mostly -- and most of the outbreaks in fruits and  
4   vegetables have just been very, very recent. So much  
5   so that many people can't believe that this can be  
6   happening, and they are getting hit with this.

7           It takes a long time to put everything in  
8   place that is absolutely necessary to attack this  
9   problem.

10          You can help us, I suppose, because the  
11   people who work for us are also people who we have to  
12   depend on to cooperate with us, as far as washing  
13   their hands, as far as using the bathrooms, the  
14   port-a-potties and all of that.

15          So it takes consumer education.

16          Another thing is that consumers in this  
17   country, unlike consumers in other countries, always  
18   assumed that the produce that they bought was  
19   absolutely clean.

20          I grew up in Brazil, and I've lived in  
21   Mexico and in Venezuela. . People there have been  
22   dealing with amoebas and the like for a long time,  
23   and it never ever dawned on anybody, who ever had any  
24   kind of education at all, to just stick their produce  
25   under water.

26          Everybody knew to go ahead and get some



1 chlorine. They used to have them in pill form, and  
2 they used to soak their vegetables for 20 minutes  
3 before they would serve them to their family.

4 Here, I had a problem with my mother. I  
5 said, "Ma, you have to put your vegetables in water  
6 with some ice and a little bit of vinegar and lemon  
7 and take a little tablet of clorox."

8 She goes, "Bleach? Oh, my God."

9 Well, in fact, when we have an earthquake  
10 here or something, we're always told to treat our  
11 water with chlorine.

12 We really need to, at this point, make a  
13 joint effort, all of us, and the people who are  
14 consumers who are also workers, whether in a  
15 restaurant, in a hospital, in a field or whatever,  
16 have to realize that they, too, contribute to  
17 outbreaks, or they also contribute to keeping our  
18 food supply safe.

19 We have to do this all together, or -- it's  
20 really a joint effort.

21 Thank you.

22 MR. NELSON: Next question. Anybody in the  
23 back?

24 MS. BRISSON: I just feel compelled to let  
25 people know that there were at least three  
26 representatives of the Senior Nutrition Community in

1 Northern California at this meeting. I'm kind of  
2 one of the last ones left, because I live here in  
3 Salinas.

4 My name is Elsa Brisson, and I'm with the  
5 Monterey County of Social Services, and I oversee the  
6 Area Agency on Aging for this County.

7 I have turned in written testimony, on a  
8 couple of the issues, and I would like to share that  
9 -- what spurs me, from Elaine, was, I still think  
10 that, when I go back to work with the clients, both  
11 in the food stamp program as well as in the senior  
12 nutrition program, I need up-to-date, quick, short  
13 information, not 29 pages, on how -- what to tell  
14 consumers about value-added products.

15 In the senior community, people are not  
16 cooking. What I see in my packet about the  
17 "Fight-bac" program is excellent. It's excellent  
18 for me as a mother of young children to take home to  
19 my home and use because I cook. A lot of my clients  
20 do not. They live in hotels. They also do not cook.

21 They get cooked food out of the pantries and other  
22 places and it's "open the bag and pour it out."

23 What I need to know -- I was on a tour at a  
24 Knob Hill Grocery Store, and I was telling them they  
25 should rinse added-value vegetables, and the salad is  
26 already in the bowl, and we just zip all the bags

1 open and eat it.

2 Who is correct?

3 So those kinds of issues need to be  
4 addressed, and they need to be addressed in short  
5 form so professionals like myself can keep a handle  
6 on the big picture, because I do not have time to go  
7 through like web sites.

8 FDA and USDA have fabulous web sites, and I  
9 have spent many, many hours looking through the  
10 research materials, but many times I get a  
11 representative saying, "Did you hear about the  
12 strawberries?" "No."

13 Today I was dealing with other issues so we  
14 need to be able to be there because I feel that I am  
15 the link between to two communities.

16 I'm a registered dietician by profession,  
17 so I just thought I wanted to be on the record, that  
18 we need it to be simple, and we need to know what the  
19 risk is, because one of the percentages that kept  
20 coming up was three percent comes from the produce,  
21 and I really do think the most important thing senior  
22 citizens die of -- the five major things are -- heart  
23 disease and cancer -- and heart disease, we  
24 definitely know, is nutritional.

25 Comparing the need to lower fat, eat more  
26 fruit and vegetables, a little bit of residue on a

1 vegetable, the risk and benefit ratios are, you know,  
2 blown out of proportion.

3 (The court reporter admonished the speaker  
4 to slow down.)

5 MS. BRISSON: I'm sorry. When I  
6 get excited, I talk too fast. I'm sorry.

7 Especially the senior community, they watch  
8 television, they read newspapers, and they don't  
9 sometimes connect the fact that the food-borne  
10 illness was in Michigan, or the eggs, like the  
11 chickens whose ovaries that have Salmonella are  
12 actually only East Coast, not the West Coast, and so  
13 they started taking all of these foods out of their  
14 diets, and sometimes I sit down and go, "Well, what  
15 do they eat?"

16 And sometimes what they are eating is  
17 refined sugars. So then I also find out they are  
18 diabetics.

19 So the issue is the risk benefit, and then  
20 to make it simple for people like me who don't really  
21 want to know the different strains of E. coli. I  
22 teach it, but I don't want to do it on a daily basis.

23 Thank you.

24 MR. NELSON: Next?

25 MR. HENDERSON: Hi. My name is Peter  
26 Henderson. I'm with Sprout House. I'm a grower,

1 packer, shipper of sprouts. We do mostly clover  
2 radish and onion. We're in the -- probably the large  
3 grower in Northern California, and Elaine, I hear  
4 your fears, and I've been doing it for 20 years, and  
5 I started out with a VW bus, doing swimming pools,  
6 and have progressed to a company with 30 employees.

7 We have a full HACCP program. We have --  
8 are not using the Bonair (phonetic), but we use a  
9 Pulse Instrument for sanitizing wash before we  
10 package our product.

11 We use Silliker Labs for our constant  
12 testing of -- normally our product. We test our  
13 drains, our wash tanks and our drums.

14 I'm really here to kind of say I think we  
15 have a good forum. I think one of the things that  
16 comes out of all of this is change. Two years ago, I  
17 never thought sprouts could even be considered a  
18 problem.

19 We could have any kind of bacterial problem  
20 that could make people ill, Salmonella or E. Coli.  
21 So I'm here to ask you, the FDA, to take the time.

22 I think we do have the regulations,  
23 whatever, that 0157:H8 -- it's a very intense  
24 document. I think we need to work together as  
25 groups, not specifically apples or sprouts, to get an  
26 overview of each industry, because each industry has

1 different problems and different needs, and we have  
2 to be able to change and to regulate.

3 You can't change regulations as fast as  
4 E. Coli 0157, or whatever the new name is going to  
5 be, or the new problem. And part of being in  
6 business is change, from blue swimming pools, VW  
7 buses to large refrigerated trucks, to 30 employees  
8 from 4, to short hair to -- you know, to making, you  
9 know, a decent living, from making nothing, living at  
10 home with your parents.

11 So change is what I can only say. I grow  
12 around 20,000 pounds a week of product. After 20  
13 years, if my product was a bad product, I wouldn't be  
14 here today.

15 So I think everybody wouldn't be here today  
16 if they didn't have a lot of faith in what they do  
17 and do a good job.

18 The real problem I kind of worry about is  
19 the people that aren't here. The people that are  
20 chopping the vegetables in the back room and throwing  
21 them in a bag and selling them.

22 But we will get to them and we will change  
23 and please have confidence in your sprout grower.

24 Thank you.

25 MR. NELSON: Next person. Another  
26 question?

1 MS. HARWOOD: I'm Janice Harwood, and I'm  
2 the Nutrition Family and Consumer Sciences Advisor  
3 with the University of California Cooperative  
4 Extension.

5 First of all, I wanted to reiterate what  
6 Mr. Riggs and several of the others have said this  
7 morning, about getting out in the field and really  
8 seeing what is already being done.

9 I had that opportunity last spring. In  
10 fact, I helped organize a tour with the cooperation  
11 of several local shippers and growers. The tour was  
12 for nutrition and health professionals, and the  
13 purpose was to educate us so that we would be able to  
14 better answer consumer questions that we get from our  
15 clients.

16 And it was very enlightening to everyone.  
17 I thought that I was pretty knowledgeable about some  
18 of the practices that were being used in the field,  
19 and I learned that there was considerably more being  
20 done than I thought was being done, and I find that  
21 the industry is very responsive to making sure that  
22 the food is safe because they are consumers, too.

23 They all take home product to eat at home,  
24 and certainly would not want to make their own  
25 families ill. So I think there is already a lot  
26 being done, and if you haven't been in -- through a

# ORIGINAL

1 processing plant, we are going to be doing another  
2 tour. The industry has been -- is willing to support  
3 a second tour.

4 I would like to invite Elaine to give me  
5 her card so that I can include her in the invitation  
6 next year, and also anyone else that would like to  
7 participate as well.

8 In my nutrition education program, which is  
9 targeting low income families, I implement the  
10 5-a-day message because it does -- it's important for  
11 improved health.

12 The objective of the program is to help the  
13 low-income consumers be able to take advantage of the  
14 best buys in the supermarket that will provide them  
15 with the most nutrition.

16 This includes increasing the consumption of  
17 fruits and vegetables, and notice I said "fruits and  
18 vegetables," not "fresh fruits and vegetables."

19 We all know that the imported produce that  
20 we get at this time of year can be much more costly  
21 because it's not in season, and people are confused  
22 about what's in season any more because it used to be  
23 that there was a season.

24 MR. GARDINE: There was a season.

25 MS. HARWOOD: Right. That there was a time  
26 when grapes weren't in the stores, that peaches



1 weren't in the stores. And we relied on other  
2 things. We relied on canned, we relied on frozen.  
3 And that is what I still encourage in this program.

4 So, I hope that, in your recommendations or  
5 regulations or guidelines that you are providing, at  
6 the international level, will certainly be of a  
7 fairly strict nature, because it does not make sense  
8 that we continue to support the other countries and  
9 be -- have this high-priced food in the supermarket.

10 I also want to encourage you to use the  
11 Cooperative Extension network of home economists. We  
12 have different titles in different States, but please  
13 use us as a means of providing consumer education.

14 I've been doing nutrition education for  
15 longer than I want to admit, and I have been giving  
16 the same food safety message for just as long. It's  
17 a simple message.

18 This pamphlet that you included in our  
19 packet today is the basic message, and if people  
20 follow this, they shouldn't have any problems, and I  
21 use that booklet in my program. I just wish it was  
22 also in Spanish.

23 MS. McDONALD: It is.

24 THE WITNESS: It is? Oh, thank you, Janet.

25 It just never ceases to amaze me that  
26 people have not gotten the food safety message, and

1 put it into practice. What I think we are going to  
2 need is some additional resources to develop  
3 strategies to change the behavior of people in the  
4 home.

5 We know most of the food-borne illness  
6 takes place in the home. It doesn't get reported in  
7 the same way, the same extent that the large  
8 outbreaks that come in at the food service level, but  
9 it's -- it just is a message that I wonder why it  
10 hasn't been put into practice. It's one thing to  
11 educate. It's another to change behavior, and we  
12 need to figure out how we can really get people to  
13 change their behavior.

14 I'd also like to encourage the industry to  
15 work with Cooperative Extension, home economists or  
16 nutrition advisors to help get their message to the  
17 consumer.

18 We have been neglected by the industry as a  
19 means of consumer -- of communicating with your  
20 customers, and it would be most appropriate to  
21 support our programs, just as it is to support the  
22 research and extension programs of the farm advisors  
23 and the agricultural agents, as they are called in  
24 other States.

25 We are looking forward to working with the  
26 local growers and shippers on the tour next year and,

1 again, if any of you want to be invited, just let me  
2 know, and we'll make sure you get an invitation.

3 MR. GARDINE: Just for the record. I want  
4 to thank you for those comments, all of which were  
5 very well taken, except that I must stress your  
6 opening comment about somehow enforcing this more  
7 strictly internationally, because of our treaty  
8 obligations and because of some of the concerns you  
9 heard raised here, that whatever program we initiate  
10 domestically, we are going to have to find a parallel  
11 way to do something similar and not tougher  
12 nationally.

13 MS. HARWOOD: That's my personal opinion.

14 MR. NELSON: Okay. Next question?

15 DR. ZAWEL: Ray, I have a couple of  
16 comments. Actually I have questions or comments  
17 really to Elaine's concerns and statements.

18 One of them is the fact that you weren't  
19 invited, and there is a tremendous amount of  
20 complaint across the industry that, "We weren't  
21 invite either," and on that note, we are on the same  
22 page, and in fact it was at our own volition, we put  
23 together a panel. FDA did not come to us and put it  
24 together. So just to make that very clear in this  
25 instance.

26 The other issue is your desire to have a

1 recommendation to eliminate microorganisms rather  
2 than reduce, and I can certainly recognize that, from  
3 a consumer standpoint, and obviously I am one also,  
4 as the rest of us are in the room.

5 But elimination is completely unrealistic,  
6 it's like setting a zero tolerance for listeria.

7 That will not engage the industry in this  
8 process, and reducing means to reduce, as the means  
9 to eliminate aren't going to be any different, but  
10 calling it elimination is just an unrealistic goal.

11 The third comment I wanted to make is the  
12 one that you stated about manure and the information  
13 that's in the guidance. There are a couple of quotes  
14 or statements that will hopefully in the future  
15 contain references, and that is the 70-day survival  
16 of E. Coli 0157:H8 in cow manure, and the one-year  
17 survival of the same organism, I believe, in sheep  
18 manure.

19 The 70-day experiment was done in a test  
20 tube, and that is the best information we have right  
21 now on 0157 and manure.

22 The one-year experiment was, although  
23 short, mentioned in the February National Advisory  
24 Committee meeting.

25 It was mentioned off-the-cuff to  
26 demonstrate the fact that we don't know what the

1 survival is of some of these organisms. The  
2 unfortunate part is that it made it in the guidance  
3 just on that very short mention, and I'm still  
4 skeptical of that information, and I hope that FDA  
5 has in fact got that reference in their hands, and  
6 has evaluated that reference with the same rigor that  
7 I evaluate information.

8 And I would encourage you, in instances  
9 like that, as well as all of us, to do -- to get  
10 ahold of that data.

11 Get ahold of the study and say, you know  
12 "What does it mean? How was this experiment done  
13 and does it demonstrate that in fact this is a risk  
14 or is there further research that's needed?"

15 And we would certainly be more than happy  
16 to be a resource to get that information to you.

17 But I just -- that demonstrates by itself  
18 that we need more science to really determine what  
19 the risks are with all of these things, whether it be  
20 manure, whether it be water.

21 The last point that I wanted to make  
22 directly to your comments was the need for  
23 pathogen-specific targeting testing.

24 It's going to be -- it's not going to be --  
25 if in fact that is advocated and that's in place,  
26 it's not going to be indicative of some of these

1 issues and you are going to miss organisms that do  
2 not have the same survival as whatever the  
3 pathogen-specific testing is going to focus on. So  
4 if you pick E. Coli 0157:H7, are you in fact  
5 guaranteed to have eliminated Cyclospora from that  
6 product?

7 And those are things we don't know, and  
8 that's why we need research to identify the  
9 appropriate organism as an indicator.

10 The other question, actually, I had for Dan  
11 -- Dan Weber was it? I can't see you.

12 MR. WINNER: Winner.

13 DR. ZAWEL: You had stated that you  
14 encouraged HACCP and trace-back. Are you -- and I  
15 just want a clarification. I wasn't quite sure if  
16 you meant that HACCP in the whole produce environment  
17 is what you are advocating, and looking for, from  
18 your suppliers?

19 MR. WINNER: Yes. I think.

20 MR. GARDINE: Can I ask you to come to the  
21 mike, please?

22 MR. WINNER: I believe it should be from  
23 the field of -- (inaudible) -- the consumer has to,  
24 in my opinion -- is that you need an (inaudible)  
25 business.

26 In a grower or packer situation that you

1     need it to their environment, so it's not someone --  
2     the guidelines are there, you create them. It's just  
3     basically the critical control points, and you can  
4     identify them and set up measurement and monitor them  
5     and I think that's an useful tool in our operation,  
6     along with sanitation, and along with GAPs and -- but  
7     not -- and I've been through packing houses, and I've  
8     been in some fields, and you know, so it's not easy,  
9     you know. Some of the -- but it's -- it's unique to  
10    whatever the operation is.

11                 DR. ZAWEL: Right, and I think that --  
12    that's what I thought. And I need to address that on  
13    behalf of the industry position from our memberships'  
14    standpoint, is that HACCP is an acronym.

15                 Good agricultural practices is an acronym  
16    and good manufacturing practices is an acronym, and  
17    what is important is what you do in your food safety  
18    program and not what acronym you use to describe it,  
19    and what I mean by that is that HACCP is a  
20    science-based system, and you identify the critical  
21    control points, and what you do about those critical  
22    control points, based on science, and so while we --  
23    the industry moves forward on these issues in a  
24    direction that is HACCP-based, under the principles  
25    that we are preventing problems, rather than testing  
26    an end point, we cannot call what we do "HACCP,"

1       because -- until we have the science.

2               And as the science is developed, some of  
3       the critical control points can be better defined and  
4       so I state that, very importantly, for the record,  
5       and for the people in this room, and for you, to make  
6       sure, instead of demanding of your -- of the people  
7       who supply to you, that you have a HACCP program, ask  
8       them instead, "What do you do to assure the safety of  
9       your products?" Get it line-by-line, and go visit  
10      them and make sure they are doing what you expect.

11             MR. GARDINE: I --

12             DR. ZAWEL: Could I add to that, for FDA,  
13      an earlier draft of this document did contain a  
14      section on HACCP. It was determined HACCP -- means  
15      Hazard Analysis Critical Control Point.

16             One of our concerns were the critical  
17      control points, the mechanisms for controlling them,  
18      currently, are not there. And it -- it would be very  
19      difficult to call this a HACCP program.

20             So that section was purposely taken out,  
21      for that very reason --

22             MS. DODGE: I'd like to respond to what.

23             DR. ZAWEL: -- because I think this is a --  
24      it's kind of a unique opportunity, at the beginning  
25      of these discussions, when all of the aspirations and  
26      points are fuzzy, and where we can find common ground



1 for agreement, because I predict that six, eight,  
2 twelve months from now, when we get down into those  
3 devilish details, there will be a lot of  
4 disagreement. FDA, like, we don't have it now.

5 MS. DODGE: We will get tougher. Consumers  
6 are also big advocates for science, and in the same  
7 way that you don't want to burden industry with  
8 unnecessary requirements that may not make food any  
9 cleaner or safer, you don't want to create a false  
10 sense of security in consumer's minds that a product  
11 is safe because the government has told industry to  
12 do it a certain way, when the government really had  
13 no basis to tell industry to do it that way.

14 So we want there to be a scientific basis  
15 for testing water, what you're testing for in the  
16 water, and I do see that it has to be  
17 product-specific.

18 In other words, it's incumbent upon the  
19 government to identify, "These are the products that  
20 are likely to be contaminated with these pathogens,"  
21 and then you test for those pathogens in those  
22 products, unlike the system that they have set up now  
23 for beef and poultry, where they are testing  
24 everything for Salmonella, as an indication for  
25 process control, where Salmonella isn't necessarily  
26 the pathogen that you would worry about in some of

1 the products that it's being tested for, and I  
2 certainly wouldn't want to see FDA make the same  
3 mistake that USDA had made.

4 Another comment I would like to make is  
5 something I forgot to make when he was up there is,  
6 also, the importance of testing in this  
7 recommendation for washing, where the recommendation  
8 is that you have progressively cleaner water for  
9 washing produce the closer it gets to the --

10 Where it gets into the hands of consumers,  
11 that's only a worthwhile recommendation if you have  
12 studies that show that contamination in the first  
13 washing -- that you might get in the first washing is  
14 going to be washed away by the final washing, and if  
15 you can't prove that, then there doesn't seem to be  
16 any -- it becomes a detriment to impose on the  
17 industry that washing requirement and make consumers  
18 think that somehow now their product is more safe  
19 because it's been washed with clean water at the end.

20 DR. ZAWEL: No.

21 MR. NELSON: Any other questions?

22 MS. TENZER: Again, I would like to --

23 MR. NELSON: Name, please?

24 MS. TENZER: My name is Gail Tenzer,  
25 Bonagra Technologies. Again, I would like to address  
26 some of Elaine's concerns.

1           As far as the washing is concerned, we are  
2     washing and disinfecting and sanitizing, as much as  
3     we can, those commodities that lend themselves to  
4     washing. There are some commodities, such as  
5     mushrooms -- well, maybe not mushrooms, but grapes,  
6     strawberries, that do not lend themselves to being  
7     washed in a packing house, and actually are only  
8     washed at the point of consumption.

9           Now, those definitely need to be washed by  
10    whoever is going to be serving them, Number 1.

11           In the second place, and as I told you  
12    before, we as a society don't have everything in  
13    place to assure that, after we've done an excellent  
14    job of sanitizing the product, unless it's packaged,  
15    that it hasn't been recontaminated, say, in a truck  
16    that was used for the transportation, or that it  
17    hasn't been somehow recontaminated at the  
18    supermarket, or in the food service establishment or  
19    whatever.

20           So in the interest of safety and caution,  
21    if you are at all in doubt, it probably -- or if you  
22    have an immune-system compromised person, it's  
23    probably a very, very good idea to go ahead and do it  
24    again, although it's not necessary to do that with  
25    the packaged products.

26           They probably know what they are doing and

1 have done more studies and everything in that  
2 direction, and I believe that those products are  
3 generally washed very well, and are safe.

4 Now, also when we're talking about  
5 processors who are receiving products that they  
6 themselves do not grow, but they are going to process  
7 them, because, again, there is always the potential  
8 of a product getting recontaminated, say, in  
9 transport, et cetera.

10 If you are going to be turning your product  
11 into juice or into a salad or anything else, then in  
12 order to avoid any kinds of problems, I would  
13 definitely resanitize the fruit before I process them  
14 and I think that -- as a processor, we have to do  
15 that anyway.

16 Then it's not as important what source you  
17 got it from. You have a better opportunity than does  
18 the guy who has bulk produce that is sending them out  
19 all over the place, selling them. He may sell some  
20 to foods services that are going to process it.

21 He may sell some to a supermarket, where  
22 somebody from a church or something is going to come  
23 and buy a whole batch of something and turn it into  
24 just juice, and a whole bunch of people might get ill  
25 because the people who turned it into juice are not a  
26 professional, such as you, and did not know how to

1 handle that fruit, and the fruit was appropriately  
2 washed and sanitized.

3 So I -- that's why I can't stress enough  
4 that everybody all along the food chain needs to be  
5 educated. This is a joint effort. I don't believe  
6 we should be pointing fingers at each other.

7 I don't think that we should use any of  
8 these things as a competitive kind of thing between  
9 imports or whatever, because, in fact, we've had  
10 outbreaks in this country from locally-grown produce,  
11 as there should have been from imported produce.

12 I have seen some impeccable plants on the  
13 other side of the border that it would probably be  
14 very, very difficult to find even here.

15 The other thing that I wanted to stress is  
16 that the -- boy, I've forgotten.

17 I know, if it was important, it will come  
18 back to me, and I'll just raise my hand again.

19 MR. NELSON: One comment to everyone.  
20 There is an address in your packet, and if you think  
21 of a comment you want to put in writing, write it  
22 down, mail it to us in Washington, the address is  
23 there. Please send it to us. It's not too late.

24 MR. GARDINE: And the docket number --

25 MR. NELSON: And the docket number. All  
26 the information is there. Yes, sir?

1           MR. BROWN: Louie Brown with the California  
2 Farm Bureau Federation. I think if any fingers need  
3 to be pointed, it does need to be point at the  
4 industry in California to recognize the apparent  
5 needs that we do indeed have the safest food in the  
6 world, which we do claim to have, but there is also  
7 more work that we need to do, and I think that is a  
8 statement that Nancy overlooked here, and that  
9 California farmers are some of the most progressive  
10 in the worlds.

11           We are already held to some of the highest  
12 regulations and standards in the world, and do  
13 produce safe food, which has been proven by science  
14 to be nutritious and healthy. So I think a hand does  
15 need to go out to the California producer for the job  
16 that they do.

17           Another point I agree with is the inability  
18 and the ineffectiveness to get the information out  
19 about meetings such as this, and that it's very  
20 difficult for anyone outside of the beltway to find  
21 out that there is a meeting coming to your back door,  
22 or even within your State.

23           That leads me to my question on how does  
24 the FDA propose to disseminate this information, once  
25 it is in final form, to growers so that they can have  
26 the guidelines that you are proposing and then

1 possibly use those? .

2 MR. GARDINE: Well, we've been working on a  
3 lot of things since October 2nd. Clearly, one of the  
4 things we're going to have to do with the help of  
5 USDA, and in the USDA, we think it will be a bit  
6 easier because we do have a very good Extension  
7 Service that is designed to work with growers, and  
8 share information.

9 We do have trade organizations if they  
10 agree with what guidance might be there. We do have  
11 State and local agencies to work through. We don't  
12 have -- you are asking now for a detail that we don't  
13 have, but, essentially, we think in the U.S. we have  
14 the mechanism, what might be a better, more  
15 challenging way is figuring out how to do it with our  
16 trading partners, and that is going to be one of the  
17 challenges facing us this year.

18 MS. FORBES: I have a question. I want to  
19 respond on one thing that you guys are talking about  
20 right now.

21 I'm Rene Forbes. I'm a farmer. I'm also a  
22 consumer. I love to eat, and I am concerned about  
23 our food supply and government rules,  
24 recommendations, suggestions.

25 So I am not a member of anybody up here. I  
26 got my information because I was a concerned

1 consumer. I went through the internet. I have  
2 friends who know I'm concerned.

3 So I network, I ask questions, and when I  
4 found out that there was a meeting, I called Mary  
5 Acton, who was the Director of putting this meeting  
6 on for FDA, but I am just another person, just like  
7 any of you out there in the audience. I went out and  
8 called her. She had a phone number, I got it off the  
9 internet.

10 I became aware of where the meeting was  
11 held. I asked her -- I told her I was going to be  
12 here and told her that I wanted to talk, and she put  
13 my name down and she came up to me, and I introduced  
14 myself to her, I signed in, and these people are very  
15 nice people, and they told me what my number was when  
16 I would talk. But that is how I became a speaker up  
17 here.

18 I was not invited. You do not have to be  
19 invited. All you have to be is a concerned citizen  
20 who has something to say, that you want other people  
21 to hear it, and that's what these hearings are about  
22 and if you every really concerned, you will be out  
23 there beating the bushes so that you can get the  
24 information to be at meetings like this, because I'm  
25 not in any of these organizations.

26 I did it just because I'm concerned about



1        what does go on. I've been in the farming business  
2        for 24 years, and I feel everyone should be  
3        knowledgeable about what's going on and that's how  
4        I'm here. Thank you.

5                MR. NELSON: Any other questions? Yes,  
6        sir?

7                MR. PEREZ: My name is Antonio Perez and  
8        I'm with the Agricultural Committee in Watsonville,  
9        and all I want to say is that farm workers have  
10       families, also, and they don't want their families to  
11       get sick.

12               They won't want to get sick themselves, so  
13       they try to do the job as best as they can.

14               And just in case, I think that the  
15       training program for farm workers would be a good  
16       idea, and especially if they can be done in Spanish,  
17       since at least in this area, most of the farm workers  
18       are Hispanics and any information that comes out in  
19       English is very difficult for them to understand.

20               So if we are to get a message out to them  
21       and for them to put in practice, then it has to be in  
22       a language where they can understand. So that's all  
23       I really wanted to recommend.

24               Thank you.

25               MR. NELSON: Any other questions?

26               MS. TENZER: All right. My name is Gail

1 Tenzer, and I did remember what I forgot to comment.

2 A number of years ago, at the United Fresh  
3 Fruit and Vegetable Association seminar in Yuma, we  
4 were taken over to the other side of the border to a  
5 Mexican-Japanese venture that was a processing plant,  
6 and it was extremely, extremely clean. It was  
7 probably cleaner than most of our hospitals.

8 Now, let us all remember the Japanese  
9 culture of being almost paranoid about infections and  
10 microbes, et cetera.

11 Now, when we saw all of this, I remember  
12 some people commenting that U.S. consumers will not  
13 pay what it costs to do that kind of a job.

14 It's a question of what our priorities are,  
15 too, and our market also demands that our food be  
16 competitive in price. We are one of the best-fed  
17 nations in the world, as far as that is concerned,  
18 and we do probably pay less for our food than many  
19 other countries do.

20 The Japanese were used to having to pay \$10  
21 for a grapefruit. And in fact, they buy our globe  
22 grapes, which are seeded, which are large, and they  
23 will take that wine grape, which is \$1.00, and they  
24 will peel it and cut it up into little pieces and eat  
25 it with toothpicks because fresh fruits and  
26 vegetables are extremely expensive.

1                   We can do a lot, but he also have to keep  
2                   in mind or bear in mind who is going to pay for it  
3                   and how much is it going to cost, and is the consumer  
4                   willing to pay that much, because, in this country,  
5                   produce is sold on a basis of supply and demand,  
6                   whereas some of the companies who are exporting to  
7                   other countries, they will -- for example, Japan,  
8                   will make certain demands on the grower and say, I  
9                   want it this way, but I am going to pay you so much  
10                  and so much a box, which is way above what we're  
11                  paying here.

12                  And that was what I had to say.

13                  MR. GARDINE: I have just been told that  
14                  the address to send comments to get it into the  
15                  docket is not available in your packages.

16                  The address is: Dockets Management Branch,  
17                  HFA-305 in parentheses.

18                  A VOICE: How fast do you think we write?

19                  MR. GARDINE: Okay. Documents,  
20                  D-O-C-K-E-T-S, Management Branch. Then, in  
21                  parentheses, their internal mailing symbol, which is  
22                  HFA, as in Harry, Frank, Arthur, dash 305, Food and  
23                  Drug Administration, Room 1-23.

24                  The street is 12420 Parklawn Drive. I'll  
25                  repeat that again. 12420 Parklawn Drive, in  
26                  Rockville, R-O-C-K-V-I-L-L-E, Maryland, 20857.

1           With the announcement -- the Federal  
2 Register announcement not in your package, neither  
3 you nor I have the docket number to reference on top  
4 of the document. I'm hoping someone will have that.  
5 But if not --

6           MR. McDONALD: I have it.

7           MR. GARDINE: Would you, please?

8           MR. McDONALD: It's Docket Number 97N, as  
9 in Nancy, dash 0451. Docket Number 96N-0451.

10          MR. NELSON: Does anybody in the back have  
11 a question? No questions in the back? Okay. Up  
12 here in the front.

13          Dr. Tenzer?

14          DR. TENZER: I would like to ask the  
15 members of the FDA, in connection with the fresh  
16 juice opinions and comments were solicited by the  
17 FDA last -- about two, three-month ago, what happens  
18 to all the comments, because we never got any  
19 information about a decision, or something like that.

20          Usually it's very helpful to talk with  
21 somebody that talks back. It's very, very important  
22 also to get the feedback because, with all due  
23 respect, to solve the food industry problems, we have  
24 to establish certain microbial reference numbers, and  
25 I don't see it coming from here now, and if the  
26 industry solicited, that's fine, but industry

1 deserves to be answered.

2 MR. GARDINE: I will, since I had nothing  
3 to do with that project, graciously defer to  
4 Dr. Vanderveen, if he wants to handle it.

5 MR. VANDERVEEN: I assume you are talking  
6 about the guidance that we put out in the end of  
7 August, and --

8 DR. TENZER: Yes.

9 MR. VANDERVEEN: Those data, along with  
10 other data that we have are being incorporated in our  
11 deliberations on our proposal for HACCP of -- for  
12 juice, and all the comments will be referenced in  
13 that Federal Register document when it's published.

14 We must go through it very carefully and  
15 consider each comment. We will not respond directly  
16 to each individual, but the comments will be  
17 addressed.

18 We probably will get a number of comments  
19 on the same subject that we will incorporate those  
20 together, and then comment on it, and it will be --  
21 there will be a proposal for juice HACCP, and it is  
22 presently going through the process of being approved  
23 for publication, and we assume it will be approved,  
24 but it has to go through the department and OMB, and  
25 that's underway at the present time.

26 MR. GARDINE: John, are we talking about a

1       proposal or a final document?

2               MR. VANDERVEEN:  There are two proposals  
3       that are coming on.  They are both proposals at this  
4       point in time.  They are -- I believe that's correct.  
5       We have not -- we have had an ANPRM, Advanced Notice  
6       of Proposed Rule Making, which goes out, and now we  
7       are going to proposal phase, and then, when we get  
8       comments, we will go to the final phase on those.

9               There are two documents coming out, one  
10       dealing with a labeling proposal, which will be --  
11       will have a sunset.  We are proposing a sunset  
12       revision, and then the other is -- and this was all  
13       laid out in the notice for comments -- excuse me --  
14       for the guidance document in August.  And then the  
15       other document was HACCP.

16              MR. BOLSTER:  When do you anticipate that  
17       it will come out?

18              MR. VANDERVEEN:  We can always be hopeful.  
19       We were hopeful it would get out before the end of  
20       the year but I'm not sure exactly when it will get  
21       there but we're hopeful soon.

22              DR. ZAWEL:  John, where is it?  Is it in  
23       OMB now?

24              MR. VANDERVEEN:  It's my opinion that it's  
25       being considered beyond the agency, but I can't even  
26       be sure of exactly where it is at this point in time.

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I don't have that precise information.

MR. NELSON: Well, if there are no  
questions -- if you have a question, raise your hand.

We are going to thank you all for coming  
today and all your comments and really appreciate  
your coming to spending the day here and hope to see  
you again.

(Time noted: 3:57 p.m.)

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STATE OF CALIFORNIA

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That the same is a full, true and correct  
transcription of said proceedings to the best of  
my ability.

Dated: December 17, 1997

*Eunice A. Pickthorn*

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CSR NO. 2598





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